DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2007

WEDNESDAY, MAY 3, 2006

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:15 a.m., in room SD–226, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Craig, Harkin, Kohl, Murray, and Durbin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. MICHAEL O. LEAVITT, SECRETARY

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning, ladies and gentlemen. The hearing for the Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will now proceed. I regret a little late start here, but we have been conferring with the distinguished Secretary of Health and Human Services, and we wanted to get some background information before coming into the public hearing. This is a very important hearing because it involves the budget for the Department of Health and Human Services, and health is our number one capital asset. Without health, none of us can function.

I could give an extensive testimonial to that over the past year, but I'll save that for another day and instead focus on the proposals for Federal expenditures. I say at the outset, as I have said privately to the Secretary, that I am very disturbed at the reduction in funds for his Department. There is a $1.6 billion reduction in funding for the Department of Health and Human Services, and that follows a pattern of reductions for—the other departments which are within the purview of this subcommittee. There have been reductions of some $2.2 billion for the Department of Education, reductions for the Department of Labor so that effectively, from the year—fiscal year 2005 until the present time, we have a reduction of $15.7 billion, and that means that there are vital programs for health, vital programs for human services which are in-

adequately funded to start with and are now really effectively starved.

The National Institutes of Health (NIH), which is the crown jewel of the Federal Government, is level funded, and that means taking into account inflation, there will be fewer grants made, and there have been enormous advances made by NIH. The leadership's been provided really from this subcommittee long before you became Secretary, Mr. Secretary. When we took the NIH budget from $12 to $29 billion, there have been remarkable advances in the research on Alzheimer's and Parkinson's and heart disease and cancer, but not enough.

As we speak, a very distinguished Federal jurist who has been named the 101st Senator as suffering from prostate cancer, and I lost my Chief of Staff, Carey Lackman, a beautiful young woman of 48 recently from breast cancer. In 1970, President Nixon declared war on cancer. If we had devoted the resources to the war on cancer which we devote toward other wars, we would have conquered cancer. In the past year, I have made the Kleenex industry wealthy, Mr. Secretary. This is a lingering aspect of chemotherapy treatment, and that brings me back to personalizing it just for a paragraph or two, but had the war on cancer been fought vigorously, I wouldn't have gotten Hodgkin's, I believe. The chances are good I wouldn't have. Well, that's the backdrop of these hearings and my views.

As I told you privately a few moments ago and I think it's worth repeating publicly, the President called in a number of committee chairmen last week for our views on what ought to be done, and when I had the opportunity to talk to the President, and I have had the opportunity to get to know President Bush rather well, he was in Pennsylvania 44 times in 2004 when he ran for reelection and I was up too, and I was with him on most of those occasions, and I have a very high regard for the President and the job he is doing notwithstanding the poll figures. Up close, he is very much engaged, very much on top of the job. The persona that comes through the news media is very very different. But at any rate, he is prepared to hear candid views even if they don't agree with his, and I told him about the $15.7 billion reduction in spending and told him what was happening in the National Institutes of Health. I know that you are not the President, and as you reminded me, you are not even the Director of the Office of Management and Budget (OMB), but you are the Secretary of Health and Human Services. What I am calling upon all of the candid officers where I have a chairmanship and can make a constructive suggestion is to carry this fight to the Director of OMB and carry this fight to the President, and no department is more important than yours. To have level funding for NIH and to have cuts in the Centers for Disease Control and Prevention (CDC) with all the work CDC has to undertake is just unacceptable.

Well, I appreciate your being here, Mr. Secretary, and I genuinely appreciate the job you are doing—leaving the Governorship of Utah, coming to Washington, tackling really big issues, and this matter of pandemic flu is of gigantic importance. Senator Harkin has been the leader, and I have worked with him as his partner, and we have moved ahead against some problems to produce $6.6

billion in funding. The potential for the pandemic flu if it strikes could be calamitous. When it has struck this country and the world in the past, millions of people have died. That's a real danger, and I am pleased to see what you are doing and what you plan to do even with major announcements to come tomorrow. Senator Murray has a time conflict, and I will yield to her at this time.

STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman. I am managing the floor for the Democrats in the supplemental and need to get back to the floor, and I appreciate the chairman yielding. I would second his statement and thank him for being the champion of NIH research, but also education and healthcare and all of the things that fall under the purview of this budget that you are presenting on behalf of the administration and echo his comments that investments in these diseases, investments in our future are absolutely critical to our Nation and the strength of our Nation in the future. I want to thank the chairman for his tremendous work on behalf of this and echo his sentiments that I am deeply concerned about the cuts that are coming. I can't stay for the questioning. I did want to submit some for the record and tell you personally that I have been out in the state talking to many seniors about the new Medicare Part D prescription drug benefit.

MEDICARE PART D DEADLINE EXTENSION

Although I voted against it, I want it to work. I want our seniors to be able to sign up for this and make it work. I am very concerned about what I am hearing from seniors as this May 15 deadline looms from seniors who can't get access or think they have signed up for something find out several weeks later they haven't. Many seniors are holding back signing up for it because they are worried about whether or not it's going to cover their drugs. I mean, you have heard all of it as well, and I hope that we can be thoughtful in our approach, and I would encourage you to look at extending the deadline—at least for those whose benefits don't begin until January of next year at the very minimum so that we don't cause a lot of seniors harm in the process. What I see is people signing up for these plans out of fear rather than out of knowledge. I think in the long run, we will all be hurt if that occurs, and I wanted to encourage you to work with us and continue to work with us. I know you are hearing some of the same things we are and really would like to see this—and to talk with you about that, but I specifically wanted to ask because we are now seeing seniors who signed up January 1 fall into the donut hole.

There is tremendous concern about those seniors who had pharmacy assistance plans who had drugs before who signed up for a drug are now falling into that donut hole. Are they considered uninsured, or are they considered insured for the purposes of being covered under the pharmacy assistance plans—and would like to get you or your staff to work with us as we try to help those seniors through that challenge right now. But Mr. Chairman, I will submit questions for the record, but I would like you and all of us to seriously look at this May 15 deadline and try and accommodate many of these seniors who are really having challenges who I think

we don't want to lose in this process, and we want to make sure that we have given them a benefit and not given them some dire circumstances. So I appreciate the opportunity to throw that out there and look forward to working with you, Mr. Secretary.

Senator SPECTER. Thank you, Senator Murray. Before yielding to Senator Craig, let me call upon our current distinguished ranking member for an opening statement. Before you walked in, Senator Harkin, I was praising you behind your back for your leadership—the number one leader on the funding for pandemic flu, and I said I was your partner, and the floor is yours.

STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Well, that's kind of you, Mr. Chairman, but I just follow your lead—that's all. If some of the reflective glory comes up, I am—that's all right, that's fine with me. Mr. Chairman, first of all, I want to thank you for your great leadership in so many areas—of course in this area of health. There is no stronger champion for the National Institutes of Health than the Senator from Pennsylvania.

I have been by his side in—well, it's now going on about 16 years now. If it weren't for Senator Specter's great leadership, we would never have doubled the funding for NIH that we did in the late 1990s and put it up where it is. Now, of course, we have some problems now in making sure we continue that funding, and of course that's one of the problems that I have with the President's budget, and I am sure the chairman does also.

Welcome the Secretary, and then we'll just get to some questions in at that time.

Senator SPECTER. Okay. Thank you very much, Senator Harkin. Senator Craig?

STATEMENT OF SENATOR LARRY CRAIG

Senator CRAIG. Well, Mr. Chairman, I want to welcome the Secretary, and I must say that these two gentlemen struggle mightily with a very tough budget that Congress and this Senate have always supported, but your environment and our environment is one that we are being increasingly squeezed out of discretionary monies by mandatory spending. Someday, we'll get brave enough to take it on in a responsible way. But until that time, the struggle of the chairman and the ranking member and this member will continue to go on because there has to be a sense of fiscal responsibility. I just came from the floor suggesting that the supplemental that we have got out there deserved to be vetoed by a President who had sent a message because it was about $10 billion out of line, and that's because we can't quit spending around here without a collective pressure being brought upon us. At the same time, there are priorities of spending that we get squeezed away from. I will say, Mr. Secretary, when I was home in the last recess, the good news—even though the Senator from Washington expresses continued concern about prescription drugs—is that you are having a phenomenal success, and I hope you will speak about it today. To stand up and bring on line a massive new program that this one is and to already be able to register the kinds of successes—someone said to me well, gee, it must have been pushed off the front

page by the price of oil. I said no, it was pushed off the front page because there was less criticism today and more praise as the results come in. I hope you will share those with us. Deadlines are important to cause people to react and to analyze and to decide on decisions that are necessary for them to make in a confused world. I will lastly say a couple of weeks ago, I am walking through the security line at the Boise Airport, and the fellow checking my ID said Senator, there are too many decisions, too many choices in prescription drugs, and I said well, then you would have preferred that we would have mandated a single program for you? Oh no, not at all.

Then I said you need to get with it. He said I am and laughed. I said you saving money? He said, a lot of money, but it was a tough choice. He said I really had to force myself to do a little studying. Thank you. I yield the floor.

Senator SPECTER. Thank you very much, Senator Craig. Senator Durbin, would you care to make an opening statement?

STATEMENT OF SENATOR RICHARD DURBIN

MEDICARE PART D FORMULARY PRICES

Senator DURBIN. Mr. Chairman, thank you very much. I would just say briefly thank you, Mr. Secretary, for being here. I think you have an awesome responsibility and some very important programs that are under your control and leadership. I would say on Medicare Part D that I will not quarrel with the premise that offering senior citizens coverage for prescription drugs is a good thing. It keeps them healthy and independent, strong, and out of hospitals and nursing homes longer. That's what they need. I do believe, though, that in my State there are still over 300,000 people who haven't made that choice. I don't know if that number has come down significantly in the last few days, but they only have 2 weeks left before they face a penalty for not making a choice. It is also a fact that those who have made a choice in terms of their prescription drug plan are going to be somewhat surprised to learn that the prices are not locked in. The prices of the drugs—in fact, the formulary—the available drugs that you can purchase under a plan can change on a daily basis, which leads to some uncertainty about their future. Many of us felt that it would have been a better approach to allow Medicare to offer one universal plan which consumers could choose if they like, allow Medicare to bargain for deep discounts in drugs and to offer them nationwide. Then if private insurers wanted to compete, they would be allowed to. That position did not prevail. So, in Illinois, it meant some 45 different choices for prescription drug plans, and some seniors struggled with them. Many pharmacists continue to struggle with them as of today.

NIH BUDGET CUTS

I would also want to echo what I know was said earlier by Senator Harkin. The pride that we have taken in Congress in the fact that the research money for the National Institutes of Health was doubled over a period of time. A former congressman from my State, John Porter, was the chairman of the Appropriations subcommittee that led that effort. He couldn't have made it without

the cooperation and enthusiastic help from the Senate side, and I think that Senators Specter and Harkin are justifiably proud of that as well. But I am troubled that we have seen that growth in NIH research stall in last year's budget and this year's budget continues. It's hard for me to believe that we are now at full capacity in terms of research for new drugs in America. I do believe that we need to expand the horizons, expand the opportunities to find cures for diseases, and this budget does not reflect that, and I hope that you will address that issue.

MEDICAL PROFESSIONAL AVAILABILITY

One other issue that troubles me is the availability of medical professionals. With an aging American population, with increased demands for medical help for all of us, we want to make certain that when we push the button in our room, a nurse will show up, that a good doctor will be there to tend to our needs, and I am worried that we are not keeping up with that demand for our society. Sadly, one of the ways that we supplement our need for medical professionals is to go overseas, and I have done it myself—to go to other countries that will send us these medical professionals. In most cases, these countries cannot afford to give up their own, but they do because of the lure of living in the United States and the attractive salaries that might be available for these medical professionals. The only morally responsible thing that we can do is to increase the number of medical professionals in America. When it came to the Nurse Reinvestment Act, which Senator Mikulski and others pushed forward, we have not adequately funded it, and I think we are going to pay a price for it in terms of medical professionals and this continuing brain drain on the poorest countries in the world that are sending us their medical professionals they desperately need.

As tough as it may be to practice medicine in the inner city of Chicago, it could not compare to practicing it in the Congo where there is one doctor for every 160,000 people, one surgeon for every 3 million. That is an impossible situation, and we make it worse because we bring those medical professionals to the United States—many times at the expense of these countries. The responsible thing for us to do is to develop our own medical professionals to meet the needs in the future. I hope that you will be able to tell us that your budget addresses that. I look forward to your testimony, and thank you for joining us today.

Senator SPECTER. Well, thank you, Senator Durbin. Well, we welcome you here, Secretary Leavitt, notwithstanding the opening statements of the Senators. You come to this position with a very distinguished record in public service—elected three times as Governor of the State of Utah, having served as Administrator for the Environmental Protection Agency and having taken over this very important job at the very beginning of the President's second term in late January 2005. We give you the floor, Mr. Secretary. Take as long as you like. Do not run the clock on the Secretary.

SUMMARY STATEMENT OF HON. MICHAEL O. LEAVITT

Secretary LEAVITT. Thank you, Senator. I will submit a formal statement for the record.

Senator SPECTER. Your statement will be made a part of the record and any other prepared statement.

FISCAL YEAR 2007 HHS BUDGET

Secretary LEAVITT. You acknowledged in a very kind way my service—previously as Governor. I will tell you that I value every day I had that opportunity. However, I will also confess to you that earlier this week, I spoke with my colleagues at HHS and told them that I am among the few people I suspect in the world who can honestly say I can think of nothing that I would rather do in my life right now than exactly what I am doing. The issues here are demanding, but they are extraordinarily important to the people of this country and, may I say, the world. I say that with a sense of gratitude and humility with being in a position to have some impact on delivering on the most noble of aspirations that our country has—our desire to see cancer cured, to see other diseases cured as well, to find ways in which we can prepare ourselves for a pandemic influenza and to do the other things that are currently my responsibility. I just want you to know that these are difficult issues, but I am grateful for the opportunity to serve the American people. The budget that I'll reflect today is a big budget. It's $700 billion. $75.5 billion of that we refer to as discretionary. Senator Craig referenced the fact that that number is being squeezed by the fact that the rest of the budget continues to grow at an alarming rate. I have a new grandson. He is now 8 months old. When he turns 35, Medicare alone—one of the programs that I am responsible to manage—will be 8 percent of our gross domestic product. By the time he retires at age 65, it will be 11 percent. I think everyone in this room knows that any nation that has one program that pays for the healthcare of those who have concluded their careers will likely not be on the economic leader board. I am deeply concerned about that as others are. It is having the impact of constraining our discretionary budgets. The budget I am here today to discuss is a deficit reduction budget. It is $1.5 billion less than the budget that I was here a year ago to discuss. You mentioned my 11 years as Governor. During that period of time, I was responsible as the chief executive of my State to balance that budget, and I know that any time you are doing a deficit reduction budget, you are dealing with programs that have been on the budget for a very good reason and you are having to basically offset good programs against good programs. There are no easy choices here. There will be disagreement on what the priorities should be. I acknowledge that, and my purpose today is only to tell you the basis on which I made decisions given the need for this deficit reduction budget. You will find new initiatives here, things that I believe are extraordinarily important and that are important to the President, things that you have talked about.

One of the things I am concerned about is our investments. At NIH, for example, we are seeking level funding at NIH, but there are new initiatives at HHS—for example, what we call critical path. Despite the fact that we have doubled the NIH budget, the number of molecules that we are able to actually take into the marketplace has been cut almost in half during that period of time. What that tells me is that we have to change the regulatory proc-

ess and find new tools. So, one of the new initiatives we call critical path is essentially 76 science projects, if you will, to find new ways of measuring the efficacy and the safety of drugs that will allow us to dramatically improve that rather dismal statistic. You will see some Presidential initiatives here that will be familiar to you, such as a continued expansion of the community health centers. You will also see bioterrorism emphasized and pandemic influenza preparedness. I hope we'll have a chance to talk at some length about our preparation. It is a very important matter, and we are giving it the highest level of priority at HHS. I have laid out the discretionary budget and asked those who helped me prepare it to use a set of principles—some things you will see follow through this entire budget. Some of those would be a pause in construction of new buildings, for example. Another thing you will see is that there are programs whose purposes have been addressed in other areas. I have discovered, like in many departments of the Federal Government, there are silos. There are places that deal in one silo with a problem and places that deal with it in another, and I have done my best to try to bring them together, and what that has allowed me to do is to find a way to be more efficient. You will see some programs with carryover funds where I have taken those funds and put them into some other purpose.

PREPARED STATEMENT

Those are the means by which I have done it. I laid out a group of principles. I have tried to target as opposed to looking at general problems. I have tried to work at prevention as opposed to just ongoing funding of dilemmas. I have tried to look for places where there was new innovation. We'll get a chance to talk about all of them. I won't take more time. I am anxious to get directly to your questions, but I do want to tell you how appreciative I am of the chance to serve the American people and to be here today to work with you to accomplish that same purpose.

[The statement follows:]

PREPARED STATEMENT OF HON. MICHAEL O. LEAVITT

Good morning, Mr. Chairman, Senator Harkin, and Members of the Committee. I am honored to be here today to present to you the President's fiscal year 2007 Budget for the Department of Health and Human Services (HHS).

Over the past 5 years, the Department of Health and Human Services has worked to make America healthier and safer. Today, we look forward to building on that record of achievement. For that is what budgets are—investments in the future. The President and I are setting out a hopeful agenda for the upcoming fiscal year, one that strengthens America against potential threats, heeds the call of compassion, follows wise fiscal stewardship and advances our Nation's health.

In his January 31 State of the Union Address, the President stressed that keeping America competitive requires us to be good stewards of tax dollars. I believe that the President's fiscal year 2007 Budget takes important strides forward on national priorities while keeping us on track to cut the deficit in half by 2009. It protects the health of Americans against the threats of both bioterrorism and a possible influenza pandemic; provides care for those most in need; protects life, family and human dignity; enhances the long-term health of our citizens; and improves the human condition around the world. I would like to quickly highlight some key points of this budget.

We are proposing new initiatives, such as expanded Health Information Technology and domestic HIV/AIDS testing and treatment that hold the promise for improving health care for all Americans. We are continuing funding for Presidential initiatives, including Health Centers, Access to Recovery, bioterrorism and pandemic

influenza; and we are also maintaining effective programs such as the Indian Health Service, Head Start, and the National Institutes of Health.

We are a Nation at war. That must not be forgotten. We have seen the harm that can be caused by a single anthrax-laced letter and we must be ready to respond to a similar emergency—or something even worse. To this end, the President's Budget calls for a four percent increase in bioterrorism spending in fiscal year 2007. That will bring the total budget up to $4.4 billion, an increase of $178 million over last year's level.

This increase will enable us to accomplish a number of important tasks. We will improve our medical surge capacity; increase the medicines and supplies in the Strategic National Stockpile; support a mass casualty care initiative; and promote the advanced development of biodefense countermeasures to a stage of development so they can be considered for procurement under Project BioShield.

We must also continue to prepare against a possible pandemic influenza outbreak. We appreciate your support of $2.3 billion for the second year of the President's Pandemic Influenza plan in the fiscal year 2006 Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Hurricane Recovery. It is vital that this funding be allocated in the most effective manner possible to achieve our preparedness goals, including providing pandemic influenza vaccine to every man, woman and child within six months of detection of sustained human-to-human transmission of a bird flu virus; ensuring access to enough antiviral treatment courses sufficient for 25 percent of the U.S. population; and enhancing Federal, state and local as well as international public health infrastructure and preparedness. We also want to work with you to ensure that this funding is appropriated prior to October 1, 2006.

The President's fiscal year 2007 budget also provides more than $350 million for important ongoing pandemic influenza activities such as safeguarding the Nation's food supply (FDA), global disease surveillance (CDC), and accelerating the development of vaccines, drugs and diagnostics (NIH).

The budget includes a new initiative of $188 million to fight HIV/AIDS. These funds support the objective of testing for three million additional Americans for HIV/AIDS and providing treatment for those people who are on state waiting lists for AIDS medicine. This initiative will enhance ongoing efforts through HHS that total $16.7 billion for HIV/AIDS research, prevention, and treatment this year.

The budget maintains the NIH, and includes important increases for important crosscutting initiatives that will move us forward in our battle to treat and prevent disease—$49 million for the Genes, Environment and Health Initiative and $113 million for the Director's Roadmap. In addition, it contains an additional $10 million for the Food and Drug Administration to lead the way forward in the area of personalized medicine and improved drug safety.

One of the most important themes in our budget is that it increases funding for initiatives that are designed to enhance the health of Americans for a long time to come. For instance, the President's Budget calls for an increase of nearly $60 million in the Health Information Technology Initiative. Among other things, these funds support the development of electronic health records (to help meet President Bush's goal for most Americans to have interoperable electronic health records by 2014); consumer empowerment; chronic care management; and Biosurveillance.

The Budget also includes several initiatives to protect life, family and human dignity. These include, for example, $100 million in competitive matching grants to States for family formation and healthy marriage activities in TANF. The President's budget also promotes independence and choice for individuals through vouchers that increase access to substance abuse treatment.

In the area of entitlement programs, I want to begin by congratulating you and other Members of Congress for having successfully enacted many needed reforms by passing the Deficit Reduction Act (DRA). DRA supports our commitment to sustainable growth rates in our important Medicare and Medicaid programs. It also strengthens the Child Support Enforcement program. The Deficit Reduction Act also achieves the notable accomplishment of reauthorizing Temporary Assistance for Needy Families (TANF), which has operated under a series of short-term extensions since the program expired in September 2002.

Medicaid has a compassionate goal to which we are committed. Part of our obligation to the beneficiaries of this program is ensuring it remains available well into the future to provide the high-quality care they deserve. With its action on many of our proposals from last year in the Deficit Reduction Act, the Congress has made Medicaid a more sustainable program while improving care for beneficiaries. The President's Budget proposals build on the DRA and include a modest number of legislative proposals, which improve care and will save $1.5 billion over 5 years in

Medicaid and S–CHIP and several administrative proposals saving $12.2 billion over 5 years.

This Administration has also pursued a steady course toward Medicare modernization. In just the past 3 years, we have brought Medicare into the 21st century by adding a prescription drug benefit and offering beneficiaries more health plan choices.

Medicare's new prescription drug benefit represents the most significant improvement to senior health care benefits in 40 years. CMS has already exceeded the enrollment target with more than 30 million beneficiaries with drug coverage as of April 18, 2006. In addition, almost 6 million Medicare beneficiaries get drug coverage from other sources such as the Department of Veterans Affairs. This brings the total to approximately 35.8 million Medicare beneficiaries who are now receiving prescription drug coverage. In most cases, their coverage is either completely new or much better and much more secure than it was before.

Savings from the prescription drug benefit have been greater than expected. CMS' Office of the Actuary initially estimated beneficiary premiums averaging $37 per month. Today, however, the average monthly premium is $25 a month. And in some parts of the country, beneficiaries are seeing premiums of less than $2 per month. In 2006, the Federal government is projected to spend about 20 percent less per person than first estimated, and over the next 5 years, payments are projected to be more than ten percent lower than first estimated. So taxpayers will see significant savings and State contributions will be about 25 percent lower over the next decade for beneficiaries who are in both Medicaid and Medicare. All these savings result from the lower expected costs per beneficiary.

Our work to modernize Medicare is not done. Rapid growth in Medicare spending over the long-term will place a substantial burden on future budgets and the economy. The President's fiscal year 2007 Budget includes a package of proposals that will save $36 billion over 5 years and continue Medicare's steady course toward financial security, higher quality, and greater efficiency.

The bulk of these Medicare savings will come from proposals to adjust yearly payment updates for providers in an effort to recognize and encourage greater productivity. These proposals are consistent with the most recent recommendations of the Medicare Payment Advisory Commission. To ensure more appropriate Medicare payments, the Budget proposes changes to wheelchair and oxygen reimbursement, phase-out of bad debt payments, enhancing Medicare Secondary Payer provisions, and expanding competitive bidding to laboratory services. Building on initial steps in the Medicare Modernization Act, the Budget proposes to broaden the application of reduced premium subsidies for higher income beneficiaries. Finally, the President's Budget proposes to strengthen the Medicare Modernization Act provision that requires Trustees to issue a warning if the share of Medicare funded by general revenue exceeds 45 percent. The Budget would add a failsafe mechanism to protect Medicare's finances in the event that action is not taken to address the Trustees' warning. If legislation to address the Trustees' warning is not enacted, the Budget proposes to require automatic across-the-board cuts in Medicare payments. The Administration's proposal would ensure that action is taken to improve Medicare's sustainability.

President Bush proposes total outlays of nearly $700 billion for Health and Human Services. That is an increase of more than $58 billion from 2006, or more than 9.1 percent.

While overall spending will increase, HHS will also make its contribution to keeping America competitive. To meet the President's goal of cutting the deficit in half by 2009, we are decreasing HHS discretionary spending. Our non-emergency request for discretionary budget authority for programs under the jurisdiction of this Subcommittee totals $61.1 billion, a decrease of $1.6 billion below fiscal year 2006. The $2.3 billion for the cost of the next phase of the President's plan to prepare against an influenza pandemic that I discussed earlier is in addition to this amount.

I recognize that every program is important to someone. But we had to make hard choices about well-intentioned programs. I understand that reasonable people can come to different conclusions about which programs are essential and which ones are not. That has been true with every budget I've ever been involved with. It remains true today. There is a tendency to assume that any reduction reflects a lack of caring. But cutting a program does not imply an absence of compassion. When there are fewer resources available, someone has to decide that it is better to do one thing rather than another, or to put more resources toward one goal instead of another.

Government is very good at working toward some goals, but it is less efficient at pursuing others. Our budget reflects the areas that have the highest pay-off potential.

To meet our goals, we have reduced or eliminated funding for programs whose purposes are duplicative of those addressed in other agencies. One example of this is Rural Health where we have proposed to reduce this program in the Health Resources and Services Administration. The Medicare Modernization Act contained several provisions to support rural health, including increased spending in rural America by $25 billion over 10 years. For example, it increases Medicare Critical Access Hospitals (CAH) payments to 101 percent of costs and broadens eligibility criteria for CAHs. Moreover, recognizing that Congress adopted many of our saving proposals last year, we are continuing to make performance-based reductions.

Our programs can work even more effectively than they do today. We expect to be held accountable for spending the taxpayers' money more efficiently and effectively every year. To assist you, the Administration launched ExpectMore.gov, a website that provides candid information about programs that are successful and programs that fall short, and in both situations, what they are doing to improve their performance next year. I encourage the Members of this Committee and those interested in our programs to visit ExpectMore.gov, see how we are doing, and hold us accountable for improving.

President Bush and I believe that America's best days are still before her. We are confident that we can continue to help Americans become healthier and more hopeful, live longer and better lives. Our fiscal year 2007 budget is forward-looking and reflects that hopeful outlook.

Thank you for the opportunity to testify. I will be happy to answer your questions.

HISTORICAL PANDEMICS

Senator SPECTER. Thank you very much, Mr. Secretary. We'll now go to the questioning by the Senators with 5-minute rounds. In the second round, Mr. Secretary, I intend to go into the budget cuts on the Centers for Disease Control and the National Institutes of Health and others which, as I have outlined earlier, I think totally unacceptable, but let me begin with the issue of the threat of the pandemic flu. There is a draft report, which has appeared publicly, where you are stockpiling 75 million doses of antiviral drugs and 20 million doses of vaccines. There are projections that there could be as much as 40 percent of the workforce absent. There are guidelines to keep people from congregating together. There is even a note about local police departments and National Guard would have the primary responsibility for keeping order, but the military would be available to assist. This sounds like a very, very stark situation. We know that when such disasters have occurred in the past, there have been millions who have been killed. One of the really important matters to be covered is to acquaint the public with what the problems are—that it may be difficult or dangerous to go to the grocery store, that it is important to have a supply of water, that there ought to be provisions made for a worst-case scenario. There have been articles, but they are buried in the newspapers, and I do not think that there is a real public understanding of the seriousness of this program. Now, what you are saying here today is going to be carried in the news media, and this hearing is being covered live on C–SPAN, so it is reaching people as we speak. Stark as it is, I think we ought to be very candid, very frank—brutally frank with the potential nature of the problem. Now, Mr. Secretary, what is the worst-case scenario? If it's as bad as it can be, how bad would that be?

Secretary LEAVITT. Mr. Chairman, pandemics happen. They have happened through all-time. You can date back to ancient Athens—25 percent of that city was wiped out because of disease. You can roll forward, and virtually every century, you will see two or three

pandemics. In the 14th century—Black Death, perhaps the best known, killed 25 million people across Europe.

Senator SPECTER. How many people died in the pandemic in the United States not long into the 20th century?

Secretary LEAVITT. Your point is a very good one. We have had 10 pandemics in the last 300 years. We have had three pandemics in the last 100 years. In 1968 and 1957—a lot of people got sick. Not many people died. In 1918, however, many people got sick and regrettably, millions died. If we were to have a pandemic of equal proportion to that which occurred in 1918, roughly 90 million people in the United States would become ill. About half of those—45 million would become sick enough that they would require some form of serious medical attention, and about 2 million people, regrettably, would die.

Senator SPECTER. Well, those are pretty stark figures—90 million, about one-third—almost one-third of the population, and you say millions would die. What basic precautions should people take?

PANDEMIC INFLUENZA PREPAREDNESS

Secretary LEAVITT. Well, for that reason, the President has asked that we mobilize the country. I have committed that we would hold pandemic summits in all 50 States. So far, we have had 46 of them. We are mobilizing State and local governments. We are also working to develop a global monitoring system.

Senator SPECTER. What should individual citizens do? Should individual citizens stock up on water? Should individual citizens stock up on food?

Secretary LEAVITT. Mr. Chairman, the preparation for a pandemic is essentially the same preparation that needs to occur in any disaster. It's a good idea to have some nonperishable food stored at your home. That would be true for a hurricane or a tornado. It would be a good idea for a bioterrorism event or a nuclear event. It would be true as well for a pandemic. It's a good idea to have a first aid kit and to have prescription drugs stocked up in a way that if you were to need your supply and couldn't get to the drug store that you would have it. It's a good idea to have thought through how you would deal with your children—if you had to alternate going to work with your spouse or if they both needed to stay home and you had to have some kind of caregiving process. It's a good idea to take the same precautions as in any other emergency situation.

Senator SPECTER. The red light went on in the middle of your answer, and I intend to observe the red light meticulously because I ask all the members of the panel to do the same, and now I yield to Senator Harkin.

PANDEMIC INFLUENZA VACCINE STOCKPILE

Senator HARKIN. Thank you very much, Mr. Chairman. Again, welcome Mr. Secretary. Again, I just want to point out that this committee—the Senate went on record 73 to 27 on an amendment offered by Senator Specter on the budget to increase our budget allocation by $7 billion for health and education programs, much of which would go to this Department to make up for a lot of the cuts that we see in this budget. Of course, we don't have a budget yet.

The House can't seem to pass one. So, I don't know what's going to happen on that later on down the pipe, but I am hopeful that that $7 billion that Senator Specter and 72 other Senators voted to support stays in there. If that's the case, then we can make up for some of the cuts that are in your budget that I think are just devastating—the cuts to Social Services Block Grants by $500 million, eliminating the Community Services Block Grant programs, the cuts—as you said, the level funding for NIH, which translates into cuts for some of NIH and for the Centers for Disease Control, the cuts on rural health programs, poison control centers, health professions trainings programs—all of these things all got cuts—all got cuts. Quite frankly, with the needs that we have out there, these cuts cannot stand, and that's why I am hopeful that we can get that $7 billion. Now, I want to follow up a little bit on the Avian Flu. I want to see if we can clarify the issue of stockpiling of antivirals. The World Health Organization recommended that countries stockpile sufficient antivirals to treat 25 percent of their populations. In your written statement, you concur with that goal. That would equate to about 80 million Americans. I understand that your Department has ordered or has on hand enough antivirals to treat about 26 million individuals, so that leaves about 50 million—60 million short. I understand that you anticipate States will order 30 million courses of antivirals. The Government will subsidize that at 25 percent of the cost. States have been asked to place their orders with you by July—by this July. The final course of treatment will be ordered using pending funds—2007—next year funds. Well now, again, I laid that groundwork to say that—are there any States that have indicated that they will not be able to order these medications because they have a lack of funds or a lack of legislative authority to do so?

Secretary LEAVITT. No State has made that statement to us at this point.

Senator HARKIN. Okay. What is your plan if States don't order these treatments by July?

Secretary LEAVITT. We intend to acquire 50 million courses of antivirals.

Senator HARKIN. You mean 50 million over the 20 you have?

Secretary LEAVITT. Let me reconcile the entire amount and then give you the timeframes. We will have by the end of 2006 the 26 million that you have spoken of. We will have by 2008, 50 million that will have been purchased by Federal money and that will be available for distribution.

Senator HARKIN. Okay.

PANDEMIC INFLUENZA VACCINE DISTRIBUTION

Secretary LEAVITT. We will make a distribution of that 50 million among the States on essentially a proportionate basis. So they will have that available to them in its entirety by the end of 2007. Each of the States then has an opportunity to supplement that—their proportionate share of that 50 million, and we will subsidize it by 25 percent up to their proportionate share of the remaining 31 million. We anticipated originally that we would ask States to make that decision by July. Since that information was provided to you, we have made a decision that we will allow them to buy off of our

order and at the same time, deal directly with the manufacturer so that they could be more efficient rather than go through us.

Senator HARKIN. My time is running out. Mr. Secretary, in the case of a pandemic, State, and local health departments will have to distribute the vaccines. Are you encouraging States to organize mass vaccination exercises during this next flu season to get ready for that?

Secretary LEAVITT. We are.

Senator HARKIN. If so, will you allow the States to use a portion of the $350 million that we allocated for that to purchase annual flu vaccine?

Secretary LEAVITT. Actually, we would prefer that they utilize the $350 million to build up the public health infrastructure and to reach deep into the community to be able to do the kinds of things that Senator Specter was talking about.

Senator HARKIN. But isn't one way to do that is to purchase annual flu vaccine and put in place an infrastructure——

Secretary LEAVITT. Oh.

Senator HARKIN [continuing]. To distribute it? That's what I am saying.

That's what I am talking about.

Secretary LEAVITT. I misunderstood your question.

Senator HARKIN. Yeah.

Secretary LEAVITT. At this point, we have not begun to distribute the stockpile of vaccine that we have. It is relatively small, but we will not release it until such time as we have seen person-to-person transmission.

Senator HARKIN. No, now we're—my time is running out, and that's not what I am talking about. What I am talking about is the annual flu vaccine.

Secretary LEAVITT. Oh.

Senator HARKIN. Is we put $350 million for—to build up State and local structures in case of a pandemic. One of the ways to test that to see if it works, to do it is to buy the annual flu vaccine and say okay, we are going to set up processes and methodologies to get that annual flu vaccine out.

Secretary LEAVITT. Third time is the charm, Senator. You got it.

Senator HARKIN. Okay.

Secretary LEAVITT. I think you finally reached me.

Senator HARKIN. So, my question—would they be allowed to use some of that $350 million to purchase the annual flu vaccine to test modalities out there to—how to get it out?

Secretary LEAVITT. I hadn't thought of that.

Senator HARKIN. Oh.

Secretary LEAVITT. It's a really interesting idea——

Senator HARKIN. Okay.

Secretary LEAVITT [continuing]. I'd be happy to give it some thought and respond back to you.

Senator HARKIN. I appreciate that. Thanks, Mr. Secretary. All right.

[The information follows:]

PANDEMIC INFLUENZA INFRASTRUCTURE

A major component of the $350 million allocated to States for pandemic influenza planning is for States to exercise their plans. States are permitted to use Public Health Emergency Preparedness cooperative agreement funds to purchase vaccine in limited quantities for the purpose of conducting drills and exercises. At this time, they are not permitted to purchase annual vaccine with the emergency supplemental funding for pandemic influenza preparedness. However, they may use some of these emergency supplemental funds during the influenza season as an opportunity to exercise mass vaccination plans.

Senator SPECTER. Thank you, Senator Harkin. Senator Craig?

COMMUNITY HEALTH CENTERS

Senator CRAIG. Thank you very much, Mr. Chairman. Mr. Secretary, during the Easter recess when I was back in Idaho, I visited a community health center, and I do that on a regular basis to see how it's working, who they are serving, how they are serving, and it is really one of those kind of unsung success stories out there that some of us fail to recognize. Obviously, this present—President hasn't failed to recognize that to lower income Americans, one way to serve them is making sure the door is open, and community health centers do that very well. This particular community health center in Nampa, Idaho told me that in the year, they had served over 25,000 people, and the place was full, the parking lot was full, and the doctors and nurses there were very pleased with the work they were doing. Should this committee be concerned that expansion of new facilities coupled with a reduction in funds for training personnel to work in those facilities will slow the service—access to service in communities that need these facilities or worse—exacerbate shortages in medical personnel across the country?

Secretary LEAVITT. Mr. Senator, as I indicated earlier, this is one of the President's high priorities, and this budget includes funds to continue forward in his goal of providing 1,200 new or expanded community health center sites. This includes enough for 300, 80 of which will be in the highest poverty counties. This is a passion for the President and for me, and we are working with every asset we have to continue moving it forward.

Senator CRAIG. Okay. So as I said, funds as it relates to the training of personnel, we don't—you don't see that as a problem in relation to standing these up and facilitating them for service?

Secretary LEAVITT. As I speak with those who run and operate these in the same way that you have, there are always needs there.

Senator CRAIG. Yeah.

Secretary LEAVITT. I would not want to say that we will have quenched that, but we do recognize that training is a component of it and want to meet those needs.

WELLNESS AND DISEASE PREVENTION

Senator CRAIG. Okay. Mr. Secretary, myself and other Senators consistently over time have introduced legislation to authorize Medicare to cover medical nutritional therapy services for some beneficiaries. However, there is generally a cost associated with any legislation, and that usually gives us problems in this area. I am one who believes that good health oftentimes brings down costs as it relates to healthcare and that we ought to be increasing advocates of that instead of repairs of broken bodies, if you will, after

the fact. Can you give me your general views based on your experience in implementing programs designed for health and wellness as opposed to programs designed to intervene or respond to long after diseases and ailments have onset?

Secretary LEAVITT. I believe, Senator, it should become our entire focus. When I say entire focus—until we begin to view wellness with the same passion we do treatment, not only will we not see improvement in our health, we will not see improvement in our fiscal health. I believe that is one of the reasons—in fact, one of the primary reasons, why the new Part D prescription drug benefit is such a historic point in time. For the first time, we have begun to provide for seniors the prescription drugs they need to stay healthy as opposed to simply treating them after they are sick. Over and over again, as I have traveled the country meeting with seniors, I have heard stories of people who have had heart operations, ulcer operations, and osteoporosis treatments that could have been prevented with a small amount of prescription drugs at the onset as opposed to the treatment at the end.

MEDICARE PART D ENROLLMENT

Senator CRAIG. Well, my time is up, but you segued nicely from my request for a response as it relates to medical nutritional therapy and to prescription drugs. Could you for a moment give us some of the current figures as to where we are with participation as to where we thought we would be and some of the savings that are now already appearing on the scene?

Secretary LEAVITT. We anticipated that in the first year, we would see 28 to 30 million people enroll. We have now exceeded 30 million. We anticipate between now and the 15 of May that we will have—I don't know exactly of course, but another couple million. If you assume that that's 32 million, there are 42 million in total who are eligible. There are 6 million who are getting coverage from either a private employer or some other source. If you add that 6 to the 32, you get 38. That would mean we have a shot at being able to have enrolled 90 percent of every senior who is eligible for this benefit during the first year. That is a remarkable achievement in my mind, and it's a tribute not just to the Centers for Medicare and Medicaid Services (CMS), but to the thousands of pharmacists, the thousands of volunteers, the tens of thousands of people all over this country who have been involved in reaching out to seniors in their homes, in their places of worship, in their senior centers. The other good news is the cost is coming down. The program is getting better everyday. The cost is coming down, and we are getting people enrolled.

Senator CRAIG. Thank you. It is a success story. We appreciate it.

Senator SPECTER. Thank you very much, Senator Craig. Under the early bird rule, we turn to Senator Durbin.

MEDICARE PART D ENROLLMENT DEADLINE

Senator DURBIN. So, Mr. Secretary, there is more to the story, and here is the rest of the story. The Bush administration says that 35.8 million Medicare beneficiaries will have drug coverage as of mid-April. The truth is 75 percent of those people—more than

26 million—already had prescription drug coverage before January 1 of this year through their employer, the VA or Medicaid. So there were 16 million Medicare beneficiaries who previously did not have drug coverage. Only half or about 9 million have signed up for the benefit. Millions need more time. In my State of Illinois, 606,000 people have not signed up for Part D, and the clock is ticking. It's less than 2 weeks away. Forty-five different plan choices, people—some of whom are flat on their back in nursing homes and in no position to make these choices—I think we have to acknowledge the obvious. Come May 15, the law will impose a penalty on a lot of people who did their best and just couldn't get this done, and I want to ask you point-blank do you think we ought to extend the signup deadline beyond May 15? Number two—should you allow senior citizens a do-over if they picked a bad plan that dropped the formulary, increased the cost? Do you think that that will be a reasonable way to deal with clearly a challenge that has not been met?

Secretary LEAVITT. Senator, millions of people—tens of millions of people—have prescription drug coverage who did not have it before. That is a great step forward, something I believe you would concur with. Let me again say that I believe that when May 15 comes, we will have reached roughly 90 percent of those who are eligible. Of the remaining 10 percent, about half of them will be a population that, granted, is very difficult to reach.

Senator DURBIN. But——

Secretary LEAVITT. We have had that problem—I want to answer your question. About half of them are in a low-income status, and we have granted them the ability if they qualify for the extra help—the people that you are most concerned about—we will not require that they wait until the next enrollment period. They will have no penalty, and they will have no wait.

Senator DURBIN. So increasing monthly premiums of 1 percent for every month past the deadline—are you going to waive that?

Secretary LEAVITT. If you are in fact a low-income eligible person, you will not have a penalty, and you will not be required to wait until the next enrollment period.

Senator DURBIN. Will the administration support extending the deadline beyond May 15?

Secretary LEAVITT. We believe that a deadline is necessary and that it is working. The Government actuary told us if we did not have a deadline, we would have substantially fewer people. We believe that the plan requires the time to mature. We think that the—that half of the people who are—who have yet to enroll will be eligible to enroll during that period once they have qualified for extra help.

Senator DURBIN. I think that we are missing the point here. Of the universe of people who did not have prescription drug coverage on January 1, some 25—let me get the figure correct here—25 percent of the Medicare beneficiaries, about 15 percent of that number will have signed up by May 15, and 10 percent will have not. So 60 percent of our goal will have been reached, but 40 percent not. You are shaking your head, but those are the numbers, and we get the report from your agency county by county. 606,000 people in my State, and we have done our best. What I say to you is I hope that you will understand their predicament, that the administra-

tion will relent and give these seniors a second chance to sign up without penalty. Second, if they have made a bad choice, I hope you will give them a chance to have a do-over, a makeover, support legislation that we have introduced. They can pick a plan that really is better for them. If I might ask one other question—I'm going to run out of time. I am worried about whether or not we are doing what we need to do for our children on our watch. I go to schools across my State, and I ask a simple question—how many here have someone in your family with asthma? You will see more than half the hands go up. You can tell by looking at the children we are dealing with obesity. We know that one out of every 160 children in America have autism at this point. How can we deal with these issues when we are facing a budget that is going to make such significant cuts in the Centers for Disease Control and Prevention, in the National Institutes of Health and that eliminates the NIH National Children's Study? How can we find out what's happening out there and really protect our children against what appears to be an onset of some terrible health challenges?

MEDICARE PART D PLAN CHOICE

Secretary LEAVITT. Senator, we do have an epidemic of obesity, particularly among our young people, and the Centers for Disease Control and Prevention does have a role as would many other agencies at HHS, and we are prepared to join with you in every way we can to assure that that occurs. It is a very serious problem. I would like to just mention one other thing on the choice of plans. A statistic I learned that I think you will find interesting—we did develop a standard plan that was recommended by the Congress. Only 10 percent of the more than 30 million people now have chosen that plan, which tells me that it was very important to people that they have a choice and that they are able to choose a plan that fits their situation. I know from signing a lot of people up that if they had just had to deal with the standard plan, no matter what it was, it would not have served them well. The plan will be simplified in the next version in the same way that the market has allowed for it to become better. We are all going to get better at this as time goes on. In 1965, Medicare became law. It got better in 1966. It got better in 1967. The plans are now maturing. The pharmacies are learning how to use the system. The consumers are now better informed. We are getting better at what we do. This is a very important milestone—undoubtedly the most important thing that's happened in healthcare in the last 40 years.

Senator DURBIN. Thank you.

Senator SPECTER. Thank you, Senator Durbin. Senator Kohl?

FDA GENERIC DRUG APPLICATIONS

Senator KOHL. Thank you, Mr. Chairman. Mr. Secretary, the FDA currently has a backlog of more than 800 generic drug applications, which is an all-time high, and FDA officials expect a record number of generic applications this year and an even larger backlog. The Congressional Budget Office estimates the use of generics provides a savings of $8 to $10 billion to consumers every year, and that doesn't include the billions of dollars more of savings to hospitals, Medicare, and Medicaid. I believe it's now more important

than ever that we speed less expensive generic drugs to market, and I would think that you agree. So do you support an increase in the FDA budget to help reduce this backlog, and how much do you believe the FDA needs to efficiently reduce the backlog and pass along the savings to our people and also to the Federal Government?

Secretary LEAVITT. Senator Kohl, I concur with you that there is a need to speed generic drugs to market. It is a good thing for consumers. It's a good thing for healthcare. We are taking steps to do just that—not only to speed them, but to prioritize them. The budget that I have proposed is the budget we have proposed. We think we can accomplish that within the budget that we have suggested.

Senator KOHL. So you are not proposing any increase in the budget to help reduce this backlog?

Secretary LEAVITT. We are putting substantial focus on it, however, I will tell you, at FDA.

Senator KOHL. I'd like to hope that's going to happen, that in fact we will get the kinds of numbers—increases that we need, that I think you believe we need, and you are saying that it's going to happen?

Secretary LEAVITT. Let me suggest one piece of information that might at least give you some insight into this. Of the 800 applications, some of them are essentially for the same chemical or same molecule. So, we have begun to focus on those on in which there is not one generic or two generics. In other words, we want to get new generics into the market as opposed to a repeat of existing molecules that have been made available in some generic form. Now, we think we can do this better, and I think we have to.

ADMINISTRATION ON AGING (AOA) BUDGET CUTS

Senator KOHL. Mr. Secretary, some of the most painful cuts in the budget are programs under the Administration on Aging, which takes a $28 million hit in programs like Meals On Wheels and family caregiver support services. That means that—well, in my State, Wisconsin senior population continues to grow from 705,000 senior citizens in 2000 all the way up to 1.2 million senior citizens estimated for 2025. The budget does not account for the growth and the need for services. In addition, this budget proposes to eliminate Alzheimer's demonstration grants. In Wisconsin, the Alzheimer's Association is in its first year of a 3-year grant where they are working in Jefferson County on a program to open a dementia care clinic at a hospital in Fort Atkinson in Jefferson County. It is the first of its kind and the only one in the area, and they would lose their funding after this year should this budget prevail. So how do you explain your plan to cut these vital programs while at the same time our aging population is growing?

Secretary LEAVITT. Senator, you have listed a number of different areas, so let me do my best to respond to them and to give you a sense of what was going on in here when I made these decisions. I asked my budget team to essentially use a series of principles. One of them I asked them is to look for one-time funds. So part of that may be one-time funds where the project was completed and hence wasn't repeated. Another principle was looking for programs where purposes were involved in a number of different places at

HHS. So, it's possible that some of those were there. There were also some funds that were carried over from existing programs that I didn't repeat. Now, I can't respond directly. If you'd like me to get to you specifically with those, I'd be happy to respond, but my guess is that we'll find that those principles are the ones that were involved in helping to make the decisions we did.

Senator KOHL. I would like some more information on those particular programs.

Secretary LEAVITT. We'll be happy to respond to that.

[The information follows:]

ALZHEIMER'S DEMONSTRATION GRANTS

For 14 years under the Alzheimer's Disease Demonstration Grant to States Program (ADDGS), demonstrations in almost every State have highlighted successful, effective approaches for serving people with Alzheimer's. Similar to Preventive Health Services, it is time to put these models and the lessons that have been learned to work by moving them in AoA's core services programs—especially the National Family Caregiver Support Progam—as a number of States have already done.

The fiscal year 2007 President's budget includes the elimination of ADDGS. This reflects that demonstration projects for individual with Alzheimer's and their caregivers are ready to be incorporated into the core activities of the National Aging Services Network.

RURAL HEALTHCARE

Senator KOHL. There are a number of programs in your Department aimed at bolstering rural health. Wisconsin, one of the biggest beneficiaries in the country, received over $600,000 from the Rural Hospital Flexibility Grant Program just last year. This funding is used at over 60 rural hospitals that serve anywhere from 10,000 to 12,000 patients every year. The President's budget proposes to eliminate the Rural Hospital Flexibility Grant Program, the rural and community access to emergency devices and area health education centers. So how are rural communities expected to meet their unique healthcare challenges when these very important resources are being severely diminished?

Secretary LEAVITT. I, like you, come from a State where rural medicine is a very important part of the social fabric of our State, and so I have become quite sensitive to this. We have adopted a slightly different strategy and that is to try to bolster the reimbursement rates for providers in those areas. I have also begun to look for places, frankly, where I wasn't able to justify or I wasn't able to see a result. We have invested about $25 billion through higher reimbursements in rural areas, and that's the way we are intending for many of those funds to be replaced.

Senator KOHL. Thank you, Mr. Chairman.

CDC BUDGET CUTS

Senator SPECTER. Thank you very much, Senator Kohl. On round two, we begin now with Mr. Secretary. With respect to the budget cuts, the Centers for Disease Control and Prevention has been cut by $67 million this year. They have enormous responsibilities in many many areas which I shall not enumerate, and now we are looking to give them even greater responsibilities if there should be a pandemic flu. Dr. Julie Gerberding, a very distinguished Director of CDC, has sat at your side testifying, preparing on this item. The physical plant of CDC was a shambles when I visited it several

years ago. Prize-winning scientists were sitting in hallways, toxic materials were not under lock and key, and we have carved out funds within our existing budget to fund almost a billion and a half dollars. Immediately, Senator Harkin and I found $137 million. Now, the budget has been cut from $159 million to $30 million—a $129 million cut. I have been lobbied very heavily by people in the Atlanta community to find the funds, but I can't find money out of thin air. How can CDC be realistically cut and their physical plant not improved given the increased responsibilities that you as Secretary are calling on them to perform?

Secretary LEAVITT. Senator, may I acknowledge that the work that this committee has done to be supportive of CDC is not just noticeable, but revered, and I also acknowledge that the budget that we are presenting to you is reduced by $179 million. Within that total reduction, the buildings and facilities as far as new construction does make up $129 million of that. We have felt in a budget with a reduction or a deficit that we have made substantial progress in this area.

Senator SPECTER. Should we stop the rebuilding?

Secretary LEAVITT. Well, we believe that we are capable of pausing on what will be a long-term strategy to continue to improve the facilities. We have made substantial progress. They are remarkable facilities, and I want to express my enthusiasm for how much the campus has been improved, and I want to acknowledge as well the role of you and Senator Harkin in accomplishing that.

Senator SPECTER. Let me ask you to submit the balance of your answer in writing so I can go onto NIH.

[The information follows:]

CDC PHYSICAL PLANT

CDC has made remarkable progress on its Master Plan with $1.2 billion invested to date to upgrade their facilities. Since 2000, CDC has initiated or completed the construction of more than 2.7 million gross square feet (gsf) of laboratory and facility space. For fiscal year 2007, we have included $30 million for repairs and improvements of CDC facilities.

Consistent across HHS, our request focuses on finishing projects that are near completion and maintaining existing facilities. No funds are requested to initiate new construction.

NIH RESEARCH GRANTS

Senator SPECTER. NIH tells us that there are going to be more than 800 applications—no, 656 fewer applications, fewer ideas submitted. I am worried that there may be some for breast cancer in that group or prostate cancer or Hodgkin's. How can the crown jewel of the Federal Government—perhaps the only jewel of the Federal Government be cut in funds?

Secretary LEAVITT. Senator, I want to tell you again I agree with you that funding new research ideas is a vital, important priority and that the fiscal year 2007 budget finances 275 more new grants. Now, one of the things you will see is that the actual number doesn't reflect it because a lot of expiring noncompeting grants diminish the number. When we implemented the effort that you instigated in this committee to double the amount of funding, there was a huge amount of new grants. So, what we are in is the first

year where there are not as many non-competing continuation grants.

Senator SPECTER. Well, there will be a lot of grant applications denied and a lot of existing grant applications denied. I get lots of letters, and one illustrates it from Pittsburgh—what am I going to do, Senator Specter, on the tremendous progress I am making if they are going to cut off the funding and the grant's going to be withdrawn? Really, Mr. Secretary, this—these are not issues that can be handled within the purview of the funds which you are allocated. We are going to have to have a fundamental reassessment as to priorities.

My red light just went on, but you—the red light doesn't apply to you, Mr. Secretary, just to my questions.

Secretary LEAVITT. I'd like to acknowledge that we are working to find opportunities for new investigators and for new innovations, and one of the things we are doing, frankly, is reevaluating the grants. After they have been concluded, then people must recompete. In some cases, there are research projects that simply don't stack up to the opportunities because we have essentially been able to get the value from them that the peer review process believes would be to our advantage. So, we have begun to redeploy that into new grants. So, the actual number of new projects is higher than it appears because of the decline in the number of noncompeting grants. The red light's on, and I am sensitive to it.

Senator SPECTER. Well, I turn now to the second round for Senator Harkin, and I am anxious to see if he follows his customary pattern of having really tough questions in the second round.

Secretary LEAVITT. I am going to watch that too.

NIH FUNDING LEVELS

Senator HARKIN. You're putting me on the spot here. Just to follow up on the distinguished chairman's line of questioning on NIH—when we worked hard in a bipartisan fashion with so many others to double the funding for NIH, it was not meant to just double it and then reach a plateau and plateau off. We did this because for years, it had been underfunded, and we wanted to get it back up to where it had been maybe 25 years ago and continue the funding up. It was not meant to get it up and say oh, now we can level off. That's what I see happening, and we are falling into the same pattern that we did 30 years ago when NIH all of a sudden had—it was getting out maybe 4 or 5 peer-reviewed grants per every 10 that came in—30 percent—40 percent—50 percent. Now, we are getting down to 10 percent again. So it's like we're plateauing off again. So we are going to do this, and 10 years from now when we are probably gone, somebody will be kind of like well, we're going to have to double the funding again—not a good way to run things. So, I kind of plead with you use your counsels within the executive branch to tell them this is just not—this is not good. We—and I think that's why we had so much support for the amendment that Senator Specter offered on the $7 billion. A lot of it had to do with we are not going to let NIH fall into that same rut again. Well, that's a statement, and that's not a question—darn it. Well, I had another statement too.

PANDEMIC INFLUENZA VACCINE

I won't get into that, but on the flu vaccine, I do want to follow up a little bit on that. I have legislation in that would provide for a free flu shot for everyone every year—free flu—the Federal Government just provides a free flu shot. Now, why is that? Well, I am thinking about the vaccines and the—we have to get the infrastructure up for the pandemic flu that may—a lot of signs say is coming. As you point out, we have pandemics every so often. The infrastructure is not there to deliver it. So, if you had a free flu shot for everyone every year, not only do you save 35,000 lives a year perhaps or at least a good portion of those, you save a lot of hospitalizations, you save a lot of money if everyone got a free flu shot every year. Plus you get the States in to think about how you get it out there. You know, how do we start inoculating people in Wal-Marts and sporting centers, high schools, maybe even churches—after church or synagogue, they could get inoculated. In other words, to set up a system so that if a pandemic hits—bang, you have got it there and you can get it out. So I hope that you will take a look at that and see if there is any merit to getting a free flu shot for everyone out there, and I don't know if you want to respond to that or not.

Secretary LEAVITT. I'd love to respond just briefly. I believe one of the side benefits of our pandemic preparedness is the ability to take the annual flu vaccine dilemma off the table forever.

Senator HARKIN. Yeah.

Secretary LEAVITT. We will have to have new capacity developed and have it operating continually to keep our capacity warm——

Senator HARKIN. That's right.

Secretary LEAVITT [continuing]. The best thing to develop——

Senator HARKIN. That's right.

Secretary LEAVITT [continuing]. Would be new annual flu vaccine.

Senator HARKIN. That's right.

Secretary LEAVITT. So, I fully believe that we will see substantial increases in the availability of annual flu vaccine. How we distribute it, what the cost is and so forth will be a matter of policy, but we do need to increase it.

DISEASE PREVENTION

Senator HARKIN. Well, I appreciate that. I will continue to push that idea that we ought to just provide a free flu shot. It's about—I estimated about—well, if you figure the flu shot's about $10 for 200 million people, that's about $2 billion a year, but then the lives you save, the decrease in hospitalizations—maybe won't cost that much, so you get a win on the other side. Let me follow up on Senator Craig's comments. I told him when he walked out I was going to follow up on that, and I think I heard you say this was—your primary concern is to get prevention out there. When you mentioned the Medicare, that 8 percent GDP now going to 11 percent, the answer is not just to provide more drugs for the elderly Part D, and I don't mean to get into that contest there, but the answer is just to start getting prevention earlier in life to our kids as they go through life. Now, you know I have been very concerned about

child obesity, diet-related chronic diseases, and one of the areas I am particularly interested in is the junk food marketing that targets kids—its impact. Last December, the IOM report, "Food Marketing to Children: Threat or Opportunity?" was released in December. It outlined a series of policy recommendations for government, the food and beverage industry, schools, parents—designed to limit junk food marketing and instead to utilize the power of marketing to promote healthier diets. What's that got to do with you? Well, the final recommendation of IOM was for the Secretary of Health and Human Services to designate a responsible agency to formally monitor and report regularly on the progress of all of the recommendations in the report. On March 3 of this year, 14 Members of the Senate wrote to you urging you to implement this final recommendation so that Congress can monitor the progress made or not made toward the goal to see whether we need to do something in that regard. Now again, I am not—don't want to put you on the spot. We have not heard back from you, but that was only March—that was March 3. But again, Mr. Secretary, does HHS have any plans to take the action recommended by the Institute of Medicine to appoint a monitoring body on food marketing to children? If you don't have that answer, just——

Secretary LEAVITT. I think I best respond to you——

Senator HARKIN. Respond to me.

Secretary LEAVITT [continuing]. In writing. I have read about your concern about this, and I have begun to make inquiries as to what the current status is.

[The information follows:]

INSTITUTE OF MEDICINE POLICY RECOMMENDATIONS

Obesity prevention is one of my top priorities. I have asked Assistant Secretary for Health, Dr. John Q. Agwunobi, to work with all of the HHS agencies and offices to explore this issue in depth, and consider appropriate actions consistent with existing authorities and available resources.

In addition, last year HHS and the Federal Trade Commission (FTC) sponsored a joint workshop on the effects of food marketing on children. On May 2, HHS and the Federal Trade Commission released a report titled "Perspectives on Marketing, Self-Regulation and Childhood Obesity" that recognizes that advertising and marketing can play a positive role in encouraging sound nutrition and physical activity.

The report includes a series of recommendations for food companies and the entertainment industry to assist Americans in identifying more nutritious, lower-calorie foods; increase efforts to educate parents and children about nutrition and fitness; and to bolster the self-regulatory strategies that are currently employed to monitor the marketing of food and beverages to youth. In addition, the Council of Better Business Bureaus and the National Advertising Review Council recently announced the formation of a working group effort to review and propose changes to the Children's Advertising Review Unit and its self-regulatory guidelines.

Secretary LEAVITT. Senator, could I just make one other quick statement on a previous matter?

Senator HARKIN. Sure.

NIH RESEARCH

Secretary LEAVITT. I'd just like to acknowledge that—the commitment that I feel to maintain the momentum of the research we have going at NIH. I'll probably be the only one who will say this is a good performance, but I have worked hard in a deficit reduction budget to make sure that we kept it at least flat. That is maybe good news only to me, but I wanted to tell you I have

worked hard on it and will continue to. I also believe that what Dr. Zerhouni is doing with respect to trans-institute projects with his Roadmap is a very important part of the future. I would like to see a greater percentage of the $30 billion that we spend there every year for research on inter-institute projects on basic science where all of the Institutes will benefit. I think that's a more efficient way than simply allocating to whatever disease or body part institute it is to have their own project, and I would like at some point to work with this committee to create a means by which that could be accelerated. We need more cross-institute work. We need to have less siloed research, multidisciplined research is clearly where we will find success in the future.

Senator HARKIN. I appreciate that. That's good.

COMPASSION CAPITAL FUND

Senator SPECTER. Thank you very much, Senator Harkin. Just one final question before we conclude the hearing—Mr. Secretary, I note that you and First Lady Laura Bush were in Pittsburgh to talk about the progress on the initiative in relating to gang control, a Capital Fund—Compassion Capital Fund program—antigang efforts through a community and faith-based organization back on March 7, 2005, and I would be interested to know what your thinking is on any progress there. The problem of gang warfare and shootings is epidemic and endemic. Just this morning, two teenagers were shot straight across from a high school in Philadelphia. The shootings are virtually a daily occurrence. Recently, there was a gunfight. Last week, two men were sentenced to life imprisonment for a massive gunfight outside an elementary school in February 2004 which killed a 10-year-old. Are the funds made available through this new program that you and First Lady Laura Bush announced having any significant impact?

Secretary LEAVITT. We are nearing the point in our process of soliciting proposals. We have an obligation to come up and review it with the committee, and we intend to do that. I think at that point, we'll be in a position to evaluate together the kinds of things those funds are being used for. We are quite optimistic about it and hopeful that we can continue the momentum of the program.

Senator SPECTER. Well, the announcement was sometime ago—March 7, 2005. Have any grants been made under the program in the intervening 15 months?

Secretary LEAVITT. We have not yet received proposals. We have an obligation to come to the committee to review them with you before we do that, and we will do so.

Senator SPECTER. Well, we have put up a fair amount of money last year, and you are asking for $35 million more this year in a budget where there are cuts on some very vital programs, so we don't want to keep those funds held in abeyance. If they can be directed effectively to juvenile gang problems, we want to do that.

Secretary LEAVITT. Thank you.

Senator SPECTER. But if the money is not going to be awarded so that we can see some positive results from those funds, we want to use them elsewhere. Mr. Secretary, thank you.

Senator Harkin?

AGING SERVICES PROGRAMS

Senator HARKIN. There was one thing I just—thank you, Mr. Chairman—that I wanted to bring up before you left, Mr. Secretary. When we first met when you came into my office when your appointment was scheduled, one of the things I remember we talked about was Systems Change Grants. Shortly after the *Olmstead* decision by the Supreme Court, Senator Specter and I started working to provide funds to help States get deinstitutionalized or to prevent institutionalization, but get people to deinstitutionalize. The *Olmstead* decision said you know, we had to provide the least restrictive environment. So we started this program called Real Systems Change Grants, and we started putting money in it to implement these programs. I believe, from all that I have known about it, it has been a success year after year. But every year, we have to fight to put the money into it. Again this year, the budget eliminates funding for the grants again—once again, so we fight again to put it in. Now, I now read that you have a new program in the area—in the administration on aging called Choices for Independence. Your budget's notes say, "It seeks to reduce the current systemic bias in favor of institutional care." Well, that's what we were doing under Systems Change Grants. So again, what's the difference? Is this new program meant to replace it, to supplement it? I don't understand, and what's the difference between the two programs? Why would you eliminate the Systemic Change programs that we have been funding and now come up with this new program?

Secretary LEAVITT. Our purpose is to continue a portion of it in the Administration on Aging. We do believe, as you have stated, the need for us to deinstitutionalize and to have people served in the communities and homes, and that's the purpose. Perhaps we could provide you with more detail.

Senator HARKIN. Well, provide me with more details because it's not just aging. I mean, these are people with—a lot of the time physical disabilities, sometimes with mental disabilities, sometimes with both, but which has been proven that in many cases can live in a community setting. But a lot of times, it takes an initial expenditure made to get that done. After they get out, they're fine. As you know, there is a bias in Medicaid. Medicaid will pay for someone to be in an institution, but that institution wants to live in a community, they don't get that Medicaid support.

Secretary LEAVITT. Something we'd like to change.

Senator HARKIN. Well, I would like to change that too. That's why we had this program. So I wish you would really look at that. We are mandated—Supreme Court mandated. We got to—they have got to deinstitutionalize. So, we need to change that bias in Medicaid, and I hope we can work with you to do that also to provide that, but I would like to know why this is different. You put it in aging, but it doesn't just cover aging, it covers everybody else. If you don't have it now——

Secretary LEAVITT. I have asked my staff to respond as quickly as possible.

Senator HARKIN. I'd appreciate that. Thank you very much, Mr. Secretary.

Secretary LEAVITT. Thank you.
[The information follows:]

AGING SERVICES PROGRAMS

Thank you for this opportunity to clarify my remarks at the recent hearing. The Choices for Independence program "complements" the Real Choice Systems Change initiative. This is a very important distinction. Allow me to explain further how the two initiatives fit together.

Since fiscal year fiscal year 2001, Congress has appropriated over $245 million for the Real Choice Systems Change (RCSC) Grants for Community Living. In implementing the RCSC program, the Centers for Medicare & Medicaid Services (CMS) has awarded over 297 grants to all 50 States, the District of Columbia (DC), and two territories. In fiscal year 2006, Congress appropriated an additional $25 million to fund a new round of RCSC grants. States and other eligible organizations, in partnership with their disability and aging communities, have the opportunity through RCSC to submit proposals to design and construct systems infrastructure that will result in effective and enduring improvements in community long-term support systems. These system changes are designed to enable children and adults of any age who have a disability or long-term illness to:

—Live in the most integrated community setting appropriate to their individual support requirements and preferences;
—Exercise meaningful choices about their living environment, the providers of services they receive, the types of supports they use, and the manner by which services are provided; and
—Obtain quality services in a manner as consistent as possible with their community living preferences and priorities.

As one component of their RCSC efforts, beginning in fiscal year 2003, CMS began partnering with the Administration on Aging (AoA) to fund States to develop Aging and Disability Resource Centers (ADRC) to streamline access to long-term supports for people with disabilities of all ages. Simplified access to services, as represented through the ADRC initiative, is a key element of a State's overall systems change efforts. AoA resources for the ADRC initiative have come from the Older Americans Act Title IV Discretionary funding.

Choices for Independence builds on the Older American's Act unique mission, to help our Nation prepare for the aging of the baby boom generation. Like the Real Choice grants, Choices addresses issues facing Americans who need comprehensive home and community-based systems of long-term care to delay or avoid nursing home placement. Choices for Independence, like RCSC, is designed to promote home and community-based care. Choices will focus mainly on linking Older Americans with available services, improving consumer-directed care, promoting evidence-based disease prevention, and targeting individuals not yet eligible for Medicaid to help prevent them from spending down to eligibility. In this way, Choices will complement the work that Real Choice grants have so effectively begun to improve long-term care (LTC) service delivery systems at the State level. In fiscal year 2007, as CMS works to implement the Deficit Reduction Act of 2005 (DRA), they will continue working with States to reform their LTC delivery systems by building on the successful aspects of Real Choice Systems Change grants.

The fiscal year 2007 budget for AoA essentially folds ADRCs into the Choices for Independence initiative. The fiscal year 2007 budget includes $28 million for Choices for Independence, including an estimated $12.5 million for ADRCs; at the same time, CMS is requesting no new funding for Real Choice Systems Change grants. After 5 years, these grants have made great strides in helping States make improvements to their home- and community-based health care delivery service systems. The initiative provided useful lessons that led to the development and implementation of the Money Follows the Person demonstration (focus is consumer-directed care) as well as the State plan options for home- and community-based services in the Deficit Reduction Act (DRA). While Choices for Independence does not currently assume funding from other agencies, AoA will continue to work closely on this initiative with CMS and the other HHS agencies that have been involved in the activities that led to its development.

Senator SPECTER. Thank you very much, Secretary Leavitt. Thank you for what you are doing on the pandemic problem, and I urge you to do more on acquainting America with the nature of the worst-case scenario—how serious it could be and what people ought to be doing individually—and your efforts to stir up activity

by state and local agencies to deal with the problem. I would appreciate your assistance, your thought on what we can do about these budget shortfalls and about what can be done on advocacy within the administration, within the Office of Management and Budget which has the final word here and really with the President himself. I think that there is not a recognition as to what this means on a lot of very difficult very important agencies like the Centers for Disease Control and Prevention. These cuts on so many of the health agencies are just unacceptable. We can't solve that this morning, and you can't solve it, and there may be—have to be some action on Congress somewhere to find something that can give so these cuts are not implemented. Thank you.

ADDITIONAL COMMITTEE QUESTIONS

Senator SPECTER. There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

HEALTH PROFESSIONALS TRAINING

Question. Mr. Secretary, I am disappointed that the budget proposal again eliminates funding for health professions training at HRSA, particularly those programs focused on diversity. Why does the administration continue to neglect these programs which play such a vital role in the education of young minority students in the health professions? What do we need to do to get the administration to match the support for these programs that exists in the Congress?

Answer. The administration prioritizes the distribution of health professionals by maintaining funding for the Nation Health Services Corps, which places physicians in underserved areas, at $126 million. There is no longer a supply problem for physicians. Improving access to health care takes a commitment to improve the distribution of health care providers so that they are serving in areas where there are unmet or under-met healthcare needs. Programs that place people in the communities that need them is the best investment. In fiscal year 2005, only 16 percent of health professionals supported by the Health Professions program entered practice in underserved areas.

MEDICARE ELECTRONIC PAYMENTS

Question. The President's budget includes a proposal to save $133 million in Medicare by requiring all providers to accept electronic payments, submit electronic claims, and accept more electronic remittance advices. These savings are dependent upon virtually all providers doing this by October 1, 2006. While I laud the goal of increasing Medicare electronic transactions, I question how realistic this is given that the majority of providers in our Nation are in small practices or are solo practitioners. Many of these providers may not have computers in their office or may be reluctant to give up paper. If the savings are not realized, Medicare claims processing contractor budgets will be shortchanged in fiscal year 2007. Given that CMS recently instructed its claims processing contractors to institute a hiring freeze on both new and replacement hires, which I understand could last through the remainder of this year, and possibly into 2007 in order to address current budget shortfalls, I am concerned with any proposal which could put their funding situation in further jeopardy. How does CMS intend to implement this proposal and achieve the estimated Medicare savings? What will the Agency do if the goal is not realized and the savings are not achieved?

Answer. Senator, I appreciate your interest in our administrative processes. This proposal to save $133 million is part of an overall effort to modernize Medicare operations and administer this program more efficiently. We are working as expeditiously as possible to implement the proposal in 2006. It builds on laws that have already been in effect for several years including the Debt Collection Improvement Act (Public Law 104–134) which requires the government to issue payments elec-

tronically, and the Administrative Simplification Compliance Act or ASCA (Public Law 107–105) which requires most providers to submit Medicare claims electronically.

CMS acknowledges that certain providers are exempt from the requirement to submit electronic claims and will continue to allow these providers to submit paper claims. However, CMS has asked the Medicare contractors to review providers submitting paper claims to see if they are actually entitled to the ASCA exemption. We expect that these reviews will contribute to the savings that CMS expects to realize next year. In addition, CMS has been taking a broad look at the full range of claims-related activities to see which could be streamlined or consolidated. For example, the Medicare contractors currently send beneficiaries a monthly Medicare Summary Notice (MSN) listing services provided. A few of these MSNs include a check to the beneficiary but most do not involve payment. CMS believes it could save between $15 and $30 million by sending these "no pay" MSNs quarterly, or maybe semi-annually, instead of monthly. Another potential area for saving resources without placing additional burdens on providers or the Medicare contractors is to require those providers who already bill electronically to receive other claims-related Medicare information and outputs electronically as well. CMS believes that it may be able to save $10 million from this initiative. While there are substantial amounts at stake, CMS is confident that it can become more efficient without jeopardizing the Medicare contractors' operations or burdening the providers.

MEDICARE INTEGRITY PROGRAM

Question. CMS partners with private entities to administer the Medicare fee-for-service program. In addition to paying Medicare claims, handling appeals and answering beneficiary and provider inquiries, these contractors are the first line of defense against Medicare fraud and abuse. Unfortunately, the Medicare Integrity Program (MIP)—which is the portion of the budget that funds these critical anti-fraud activities—has been capped by statute since fiscal year 2003. I am pleased the President's fiscal year 2007 proposal supports an increase for Medicare Part A and B Program Integrity efforts. However, I am concerned with funding for these activities this year. While I understanding there are no new dollars right now, I believe it is important to find ways for these contractors to operate more efficiently and effectively. One way to do this is for CMS to give these contractors greater flexibility to manage their MIP budgets. Currently, the Agency does not allow its contractors to transfer funds among MIP program lines if the total funds to be transferred exceed 5 percent of the total funding. In these cases, the contractors must request approval from CMS, which can take months and exacerbate funding problems. This Committee included report language in our fiscal year 2006 spending bill urging CMS to give its contractors this much needed budget flexibility. While CMS has granted its contractors flexibility to manage their program management budgets, they have not done so for MIP. Given the tight budgets contractors are currently facing with MIP dollars, will you consider giving these contractors greater flexibility so they can best manage their budgets to match programmatic needs?

Answer. Although you are correct that the Health Insurance Portability and Accountability Act of 1996 (HIP AA) capped MIP funding at fiscal year 2003 levels, Congress provided an additional $100 million in 1-year mandatory funding for fiscal year 2006 in the Deficit Reduction Act of 2005 (DRA) for the new Parts C and D workloads. As you stated, the fiscal year 2007 President's budget includes a proposal to increase MIP funding over the fiscal year 2003 capped level by $85,634,000 in discretionary funding.

CMS requires all five major MIP functions (Medical Review, Benefit Integrity, Provider Education & Training, Provider Audit, and Medicare Secondary Payer) in order to have a robust arsenal in the fight against fraud, waste, and abuse. As you have noted, CMS is limited in its ability to shift MIP funds since we must ensure that a multi-faceted approach is maintained. In the last couple of years, CMS has increased this flexibility somewhat for the MIP contractors. For example, workload levels in Medical Review and Local Provider Education & Training (LPET) are scalable to a certain extent. During the budget formulation process, contractors determine the type and level of effort they will be able to provide given the available resources. As problem areas/issues surrounding their respective providers change, the contractors can revise their Medical Review and LPET strategies and shift the funding between the two functions as necessary.

As a matter of routine, CMS expects the contractors to keep the agency informed of their changing resource requirements before they are in a deficit situation. CMS is then able to work with the contractors to identify workloads that can be altered

or areas with surplus funding that can be shifted while still achieving CMS' goals and objectives. In limited cases, CMS is even able to provide additional funding.

OFFICE OF MINORITY HEALTH

Question. Mr. Secretary, I am concerned that the budget proposal reduces funding for the Office of Minority Health by $10 million. In the face of a widening health status gap, how does the administration justify significantly reducing the budget of an office who's mission is to lead the Department in the elimination of health disparities.

Also, in the fiscal year 2006 bill, the legislation calls for a renewed focus on OMH's support for historically black medical schools. Can you tell me the status of this effort?

Answer. The Office of Minority Health (OMH), part of the Office of Public Health and Science (OPHS) in the Office of the Secretary, advises both the Secretary and OPHS on public health program activities affecting racial and ethnic minority populations. The fiscal year 2006 appropriation for OMH included a one-time congressional earmark in the amount of $10 million, which was not continued in the fiscal year 2007 President's budget.

OMH recognizes the important role that historically black medical schools play in increasing minority representation in the healthcare workforce, and in providing needed services to minority communities. Therefore, OMH encourages minority serving institutions of higher education (including historically black medical schools) to apply for grant programs supported by the Department of Health and Human Services (HHS). In fiscal year 2006, OMH has received proposals from three historically black medical schools; these proposals are currently under review for funding consideration. In addition to its own support, OMH is also working with other HHS Operating Divisions to enhance Departmental opportunities to support these institutions.

NIH SLEEP DISORDERS CONFERENCE REPORT

Question. Mr. Secretary, during the National Institutes of Health's Frontiers of Knowledge in Sleep and Sleep Disorders conference in March 2004, Surgeon General Carmona gave remarks on the profound impact that chronic sleep loss and untreated sleep disorders have on all Americans and that dissemination of the existing body of medical knowledge regarding sleep and sleep disorders is critically important. What are the prospects for development of a Surgeon General's Report on Sleep and Sleep Disorders?

Answer. The Office of the Surgeon General (OSG) is studying this topic as a potential subject for a Surgeon General's Workshop or Surgeon General's Conference. In addition to the comments he made at the March 2004 NIH conference on Sleep and Sleep Disorders, Surgeon General Carmona also provided information regarding healthy sleep habits in a December 29, 2005, press release, "Tips for Parents of Teenagers," as part of The Year of the Healthy Child. In March 2006, OSG staff attended a scientific workshop on "Sleep Loss and Obesity: Interacting Epidemics" to gather more information and identify leaders in this field. In addition, OSG staff members have met with medical intern and resident advocates to discuss their prolonged work hours, and the potential impact on patient safety brought about by sleep loss in this population.

UNDERAGE DRINKING PREVENTION

Question. In February, the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD), led by SAMHSA, released "A Comprehensive Plan for Preventing and Reducing Underage Drinking." The plan sets three performance targets for 2009: reducing the prevalence of past month alcohol use by those aged 12–20 by 10 percent; reducing the prevalence of those aged 12–20 reporting binge alcohol use in the past 30 days by 10 percent; and increasing the average age of first use from 15.6 to 16.5. These are modest goals, and they expire in just 3 years. It is well recognized, however, that reducing underage drinking will take a concerted effort over many years—certainly more than 3—and no one should be satisfied with 10 percent reductions. Why didn't ICCPUD set more ambitious, longer-term targets? Would you consider doing so in your next annual report?

Answer. The targets set forth in the Comprehensive Plan for Preventing and Reducing Underage Drinking are ambitious, yet achievable, particularly considering underage drinking rates have remained essentially unchanged for over a decade. The targets in the plan, which are to be measured over the 5 year period from 2004 to 2009, represent an ambitious first step in addressing what has been a serious and persistent problem in our country. It is relevant to note that Mothers Against

Drunk. Driving (MADD) has recently adopted targets that are in the same range, including a 3-year goal of reducing the proportion of 16 to 20 year olds who drink alcohol and/or engage in high risk drinking by 5 percent by 2008.

While the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) and SAMHSA believe that the current 5-year performance targets set forth in the plan are ambitious, these targets will be revisited during the development of the next annual report.

Question. One of the expected benefits of forming the ICCPUD was that it would result in fewer duplicative efforts in the area of underage drinking. The idea was that as the many Federal agencies with a stake in this problem learned about each other's efforts, they would discover where their efforts overlap and, as a result, eliminate redundancies. Has this occurred? Can you provide concrete examples in which agencies have streamlined their anti-drinking activities?

Answer. Since the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) was created in 2004, the member agencies have worked together to conduct an inventory of Federal underage drinking programs, develop the Comprehensive Plan for Preventing and Reducing Underage Drinking and annual report, support a national meeting of the States, support town hall meetings across the country, and create a government-wide website. Through these activities, the member agencies have gained a greater understanding of the science related to underage drinking, as brought to the group by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and have enhanced their understanding of each other's activities.

The ICCPUD agencies are using this .knowledge to support each other's activities, as exemplified by the recent town hall meetings funded by SAMHSA. These meetings were used to distribute research developed by NIAAA, and were strongly supported by a number of key ICCPUD partners, including the Office of Juvenile Justice and Delinquency Prevention (OJJDP), the Office of Safe and Drug Free Schools (OSDFS), and the National Highway Traffic Safety Administration (NHTSA). Several of these agencies encouraged their regional and State counterparts to support and participate in the Town Hall meetings. NHTSA used the meetings broadly to encourage the use of the HBO documentary, *SMASHED: Toxic Tales of Teens and Alcohol* and its accompanying educational package to facilitate and stimulate dialogue about future evidence-based underage drinking prevention action in local communities.

The Centers for Disease Control and Prevention (CDC) and SAMHSA Center for Substance Abuse Prevention (CSAP) were both considering alcohol epidemiological activities in the States. As a result of work with ICCPUD, each agency became aware of the others' plans and avoided duplication of effort. CDC contributed to the development of the request for proposals issued by CSAP. This collaboration ensured that the CSAP funded program will be consistent with CDC's efforts.

Question. It is my understanding that the Surgeon General intends to issue a first-ever "Call to Action" on underage drinking prevention sometime this spring. What is the status of the "Call to Action" and its expected release date?

Answer. A Call to Action working group has developed a draft Call to Action, which will be reviewed by the Interagency Coordinating Committee on the Prevention of Underage Drinking (ICCPUD) member agencies in addition to the Department of Health and Human Services. The Surgeon General is committed to releasing the Call to Action at the earliest possible time.

PANDEMIC INFLUENZA PREPAREDNESS

Question. Congress has appropriated $350 million for assistance to the States and localities for pandemic preparedness. The goal of that program is to assure that all localities meet a minimal level of preparedness. Is the Department planning to create a single, core set of performance standards that all jurisdictions must strive to achieve with these funds?

Answer. As part of the Public Health Emergency Preparedness Cooperative Agreement, CDC in conjunction with State and local public health agencies and laboratories, national partner organizations, and Federal agencies, developed performance measures for overall public health preparedness. These measures are for all-hazards, including pandemic influenza.

Question. As part of the initial ($100 million) funding that the Department is allocating to localities for preparedness, grantees are expected to perform some kind of preparedness exercise. Will the Department be reviewing the after action reports from these exercises? And if so, what resources (financial and personnel) has the Department set aside to provide technical assistance to the States to help them mitigate the deficiencies found in these exercises?

Answer. All States submitted draft pandemic influenza preparedness and response plans to CDC in July 2005. As part of the $100 million emergency supplemental funding, the Department, primarily through CDC project officers and Subject Matter Experts, will assist in developing, conducting, and evaluating various aspects of the pandemic influenza plans through the use of exercises. As part of the award of the remaining $250 million in pandemic influenza supplemental funding, States will receive funds to "fill gaps" identified during the initial round of support. "Gaps" will be identified through two processes: first, by analyzing a comprehensive assessment conducted by local health departments measuring the many components of comprehensive influenza preparedness, and second, by analyzing results of exercises. Ongoing technical assistance will by provided by CDC.

Question. How much of the $350 million has been released to the States and localities? By when does the Department expect these jurisdictions to have spent the funds? When will the remaining $250 million be made available to the States and localities? Is there an expectation that the total $350 million must be obligated or expended by the end of fiscal year 2006? If so, is this a realistic expectation?

Answer. States were awarded $100 million on March 7, 2006 to conduct planning for pandemic influenza preparedness. Eighty percent of those funds were restricted pending receipt of their supplemental applications. The applications have been received and evaluated and CDC is in the process of releasing many of the restrictions. We anticipate releasing most of the remaining restrictions by May 17, 2006. The remaining $250 million will be awarded later this summer. CDC does not anticipate that all funds will be expended by the end of the budget period. Recipients of funding may request for consideration that carryover funds to be awarded the next budget year.

Question. Given that one of the most critical aspects of preparedness will be the ability of local jurisdictions to rapidly distribute a pandemic vaccine, will the Department encourage States to organize mass vaccination exercises during the next flu season to test their distribution plans? If so, will the Department allow the States to use a portion of the $350 million to purchase annual flu vaccine?

Answer. States are permitted to use Public Health Emergency Preparedness cooperative agreement funds to purchase vaccine in limited quantities for conducting drills and exercises. They are not permitted to purchase vaccine with the emergency supplemental funding for pandemic influenza preparedness. However, they may use some of these emergency supplemental funds during the influenza season as an opportunity to exercise mass vaccination plans.

PANDEMIC INFLUENZA VACCINE

Question. The U.S. Government will be contributing to the expanded production capacity of several manufacturing companies, who will use that capacity to produce and market seasonal flu vaccine in the absence of a pandemic. Given this unprecedented public investment in private corporations, is the Department taking steps to assure that the price charged public programs (e.g., Medicaid, Medicare) for seasonal flu vaccine is reflective of this investment?

Answer. Our goal is to be able to produce enough vaccine for every American within 6 months of a pandemic outbreak. To accomplish this goal, we have focused our efforts on developing a cell-based vaccine for influenza. Without this investment in new technologies, we will not be able to produce enough vaccine in the event of a pandemic. Another key element of our plan is to ensure that manufacturers expand capacity in the United States. It is our hope that these manufacturers will produce seasonal influenza vaccine in the absence of a pandemic, allowing us to provide coverage to more Americans.

PANDEMIC INFLUENZA SURGE CAPACITY

Question. Which HHS agency is in charge of assuring States and localities create the surge capacity for treating people who become ill during a pandemic?

Answer. The Office of Public Health and Emergency Preparedness (OPHEP) is the lead office in HHS for ensuring that States and localities create the surge capacity for treating people who become ill during a pandemic. OPHEP works closely with both HRSA and CDC to ensure that funding through the State and local cooperative agreements enhance surge capacity and pandemic influenza preparedness.

Question. Is the Department providing specific guidance and performance measures with respect to creating surge capacity? Has the Department estimated the cost of creating a minimum level of surge capacity?

Answer. An influenza pandemic in a large number of communities simultaneously would make the need for expanded medical surge capacity critical. The 2005 cooperative agreement guidance for the Health Resources and Services Administration

(HRSA) National Bioterrorism Hospital Preparedness Program provided performance benchmarks on surge capacity, including influenza. Specifically, grantees are required to establish systems that, at a minimum, can provide triage treatment and initial stabilization, above the current daily staffed bed capacity, for the following classes of adult and pediatric patients requiring hospitalization within 3 hours in the wake of a terrorism incident or other public health emergency—500 cases per million population for patients with symptoms of acute infectious disease—especially smallpox, anthrax, plague, tularemia, and influenza.

In addition, the National Strategy for Pandemic Influenza Implementation Plan released on May 3, 2006, includes guidance to Federal departments and agencies, State and local government, the private sector, and the public about how to prepare for a pandemic. With respect to surge capacity, the plan includes a number of actions (with performance measures) on which HHS will collaborate with our partners at the Federal, State, local, and tribal levels and in the private sector. These include developing protocols for changing clinical care algorithms in settings of severe medical surge (action 6.3.4.1), strategies for and protocols for expanding hospital and home health care delivery capacity (action 6.3.4.2), policies and protocols for emergency reimbursement or enrollment in Medicaid and State Children's Health Insurance Program that are appropriate for a pandemic (action 6.3.4.3), and ensuring that Federal medical assets are prepared to deploy to augment State and local capacity (actions 6.3.4.3 to 6.3.4.7). The Department is currently preparing the plan to implement these actions within the timelines specified in the National Strategy for Pandemic Influenza Implementation Plan.

PANDEMIC INFLUENZA PREPAREDNESS PLAN IMPLEMENTION

Question. While significant funds are being invested in preparedness, when a pandemic hits the costs for Federal, State, and local governments will be significantly higher. Has the Department made an estimate of what the cost would be to implement its pandemic preparedness plans? For example, is there an estimate for what the actual pandemic flu vaccine will cost once it is available? Has the Department asked States and localities to estimate the costs of responding to the pandemic, as opposed to planning for one?

Answer. It will be difficult to estimate with certainty the costs of implementing our pandemic influenza plans because each State and local preparedness plan is unique and because we do not know if we will be responding to a mild or severe pandemic. We are currently focusing our efforts on preparing for a pandemic to mitigate costs during an outbreak by ensuring enough vaccine for every American six months after human-to-human transmission, enough antivirals for 25 percent of the population, and. a stockpile of 20 million courses of pre-pandemic vaccine: We are also enhancing domestic and international surveillance to quickly detect a pandemic to slow its spread. We are working closely with States and local communities as they plan for a pandemic and to exercise those plans.

UNINSURED ACCESS TO PANDEMIC INFLUENZA TREATMENT

Question. Hospitals and other health care providers will bear the brunt of costs associated with a pandemic. During a pandemic we need to make sure that those who are uninsured are not deterred from seeking necessary care as early as possible. At the same time we don't want hospitals to have even higher levels of uncompensated care that could threaten their long-term financial viability. Has the Department considered what policies and funding might be needed to address this problem?

Answer. As described in the National Strategy for Pandemic Influenza Implementation Plan, HHS will work with State Medicaid and SCHIP programs to ensure that Federal standards and requirements for reimbursement or enrollment are applied with the flexibilities appropriate to a pandemic, consistent with applicable law. In addition, we are also examining the recommendations of Federal Response to Hurricane Katrina: Lessons Learned report to determine what policies might be needed to respond to public health emergencies, including a pandemic.

PANDEMIC INFLUENZA RESPIRATOR MASKS

Question. Last week the Institute of Medicine issued a report saying the respirator masks and surgical masks should not be re-used. The report also suggested that, as part of a larger strategy of infection control, N–95 respirator masks would offer some protection of health care workers. The WHO recommends use of these masks in a health care setting. How many N–95 masks does the United States now have stockpiled? How many N–95 masks are on order for the stockpile? Does the Department have an estimate of how many masks would be needed in the

healthcare system during a pandemic, when manufacturing and distribution of such masks may be hard to accomplish?

Answer. The Strategic National Stockpile has approximately 9.1 million N–95 masks on hand and 98.4 million N–95 masks on order. The Centers for Disease Control and Prevention estimates that up to 1.5 billion surgical masks and over 90 million N–95 respirators would be needed for the healthcare sector in the event of a severe pandemic. HHS purchased 150 million surgical masks and N–95 respirators in fiscal year 2006. The Federal Government, States, and the private sector share responsibility in ensuring an adequate level of preparedness. States have access to funding from Health Resources and Services Administration's (HRSA) National Bioterrorism Hospital Preparedness Program to address these surge capacity needs.

MEDICARE INTEGRITY PROGRAM

Question. The Congress has provided significant funding, both mandatory and discretionary, to help CMS combat the unacceptably high payment error rate in the Medicare and Medicaid programs—literally hundreds of millions of dollars even after you have made some progress in reducing the error rate. Reportedly, over 90 percent of the Medicare Integrity Program funds, $720 million per year have been diverted to fiscal intermediaries and carriers doing routine claims processing, leaving about $50 million per year for the targeted error rate reduction contracts. What is the rationale for this diversion of resources from fraud and abuse activities?

Answer. MIP funds are not used by fiscal intermediaries and carriers in the performance of routine claims processing. Separate funding under the Program Management account is set aside for that purpose. These contractors, however, have historically been the first line of defense in the fight against fraud and abuse. Under the MIP, they have conducted medical review, fraud review, cost report audit, provider education and other activities identified in the statute. All of these activities are intended to insure that payments are made properly and that inappropriate payments are recovered. Under the medical review/local provider education program, FIs and Carriers are evaluated on their ability to reduce the improper error rate.

Additionally, a significant portion of the $720 million in MIP funding is used by a host of specialty contractors, most notably the Program Safeguard Contractors, whose sole focus is fraud and abuse activities.

MEDICARE IMPROPER PAYMENTS

Question. The Congress just appropriated $100 million this year for fraud and abuse activities in the new Part D prescription drug program. What are the Department's plans for using this money to address payment errors in the Part D program? When do you intend to commit funds this fiscal year?

Answer. The $100 million appropriated in the Deficit Reduction Act (DRA) will be used for many different purposes to maintain the integrity of the prescription drug benefit and fight against fraud and abuse from all sources. CMS is in the process of committing the funds provided in the DRA and plans on using all of the funds by the end of the fiscal year.

CMS has developed a comprehensive plan for a Part D oversight program building off the approach that has worked successfully for Part A and Part B. CMS has established this plan in an effort to ensure that the funding provided in the DRA will help to combat fraud, waste, and abuse associated with the new prescription drug benefit. We have included strong safeguards in areas where we identified vulnerabilities, including eligibility, the bidding process, beneficiary plan, and retail pharmacy fraud, incentives to reduce cost and cost sharing, formulary development (kickbacks), and misuse of Part D beneficiary lists. This program will ensure that Part D contractors and other program stakeholders meet all applicable statutory, regulatory and program requirements.

CMS is expanding its efforts in fighting fraud and abuse in Medicare by using State of the art systems designed to prevent problems and maintain integrity for the new Medicare prescription benefit. A portion of the funding appropriated in the DRA will be used to develop and/or maintain the following program integrity systems:

—*Risk Adjustment System (RAS)*.—The system intended to vary the Federal share of premiums based on factors that are beyond the control of the drug plan;

—*Medicare Advantage Prescription Drug (MARx) System*.—A stand alone system that will include the processing of all enrollment/disenrollment transactions associated with the Part D Program;

—*The Drug Data Processing System (DDPS)*.—The system that collects, maintains, and processes information on all Medicare covered and non-covered drug events for Medicare beneficiaries participating in Part D; and

—*The Medicare Beneficiary Database (MBD)*.—The database that houses Medicare beneficiary enrollment information.

CMS has contracted with program integrity contractors, known as Medicare Drug Integrity Contractors (MEDICs), to assist the Agency in overseeing the Medicare Part D program. Part of the $100 million will be used to establish and support three MEDICs in the regions, in addition to the Eligibility and Enrollment MEDIC that began on November 15, 2005. The MEDIC contractors will:

—Analyze data to find trends that may indicate fraud or abuse;

—Begin to investigate potential fraudulent activities surrounding enrollment, the determination of eligibility, or the delivery of prescription drugs;

—Investigate unusual activities that could be considered fraudulent as reported by CMS, contractors, or beneficiaries;

—Conduct fraud complaint investigations; and

—Develop and refer cases to the appropriate law enforcement agency as needed.

In addition, CMS will support compliance activities to combat fraud, waste, and abuse in association with the drug benefit. These efforts will include the following strategies: (1) Part D compliance monitoring; (2) accreditation organization validation studies for Medicare Advantage plans; (3) Part D auditing; (4) other compliance and monitoring strategies; and (5) compliance and oversight training for Medicare Advantage plans.

CMS continues to work to ensure the integrity and validity of the data for the prescription drug benefit. The funding provided in the DRA will be used to monitor and evaluate prescription drug plans and Medicare Advantage plans to maintain data integrity. CMS' monitoring activities will include reviewing the plans' pricing and formulary to ensure that they follow the guidelines that have been established. In addition, CMS will review the data by performing payment validation of the plans.

CMS will also use part of the $100 million to comply with the improper Payments Information Act of 2002 (IPIA). CMS is building on its current program integrity efforts by implementing new steps to analyze program data to detect improper payments and potential areas of fraud and abuse in the Medicare and Medicaid programs more quickly and accurately. CMS is using these analyses to more effectively educate providers and beneficiaries about ways to prevent and minimize waste, fraud, and abuse. CMS' program integrity efforts are being expanded beyond fee-for-service Medicare to encompass oversight of Part D prescription drug benefit and the new Medicare Advantage plans.

The last activity that will be supported by the funding provided in the DRA are audits. These audits will include financial audits of at least one-third of all Part D organizations' financial records including bids, data relating to Medicare utilization and allowable costs as mandated in the MMA. In addition, CMS will use the funding to audit one-third of the Medicare Advantage plans for adjusted community rates and perform various cost plan audits.

Question. The fiscal year 2006 Senate bill and conference report encouraged CMS to move forward on a $3 million demonstration of the use of data fusion technology to detect payment error and fraud and abuse in the Medicare program. We understand that the agency is moving forward with a data fusion and analysis project to identify improper payments to providers from Medicare using data sources outside of current fraud recovery efforts. What can you do to get this program moving forward more quickly?

Answer. CMS will be competing contracts among the MEDICs to support and develop the Integrated Data Repository and an overall data infrastructure to support CMS fraud, waste and abuse efforts. This effort requires significant resources and will be funded with the $3 million referenced in the Senate and conference reports and through the 1 year MIP funding provided in the DRA. We anticipate that this effort will integrate Medicare fee-for-service data, prescription drug data, and Medicaid data into one central repository.

CMS—STATUS OF QUALITY DEMONSTRATION PROJECT

Question. Mr. Secretary, last year alone there were over 1.3 million new cases of cancer diagnosed in America—I can't think of a single family who hasn't had a friend or family member affected by this terrible disease. The status quo is simply not acceptable. The last 2 years your department has taken targeted regulatory action to prevent any access disruption through a demonstration project to support the development of quality-based payment policy. I strongly urge you to continue this

important program and begin to move towards a permanent funding solution that will preserve patient access to community cancer care. Do you have any updates for the committee as to the status of the quality demonstration project?

Answer. CMS is very focused on creating a payment system that offers better support for the delivery of high-quality, low-cost care as well as improving the benefits available to America's seniors to prevent disease complications and live longer healthier lives. CMS has worked closely with the AMA, AQA, and MedP AC among others to develop consistent and effective ways to measure the quality of care.

We believe the oncology community is pleased with the improvements made in this year's oncology demonstration project. This project will enable us to capture more specific information about cancer patients including their treatments and whether current cancer care represents best practices and is provided in accordance with accepted practice guidelines.

After reviewing this year's data, we will be able to make decisions about the continuation of the demonstration project and what additional improvements or modifications are necessary for 2007.

CMS—ADEQUATE PROVIDER REIMBURSEMENT

Question. Mr. Secretary, when it enacted MMA, Congress established ASP as the reimbursement metric for prescription drugs covered under Part B of Medicare. My concern is that CMS has continued to resist using its administrative discretion to correct an ASP calculation problem that thwarts the clear legislative intent underlying the shift to ASP-based reimbursement. I am referring to CMS's insistence that it cannot exclude the prompt pay discounts that manufacturers give wholesalers from the calculation of ASP because the term "prompt pay discounts" appears in the list of price concessions that the statute says are to be netted out when ASP is calculated.

Wholesaler prompt pay discounts reward the timely completion of the wholesaler's product purchase from the manufacturer, constitute an integral part of the revenues received by wholesalers for their services, and, in my experience, are not passed on to the wholesalers' customers. By insisting that wholesaler prompt pay discounts be netted out of ASP, CMS has undermined Congress' intent that payment at ASP + 6 percent should cover physicians' drug acquisition costs, allow for a reasonable level of pricing variability in the nationwide drug market, and provide compensation for drug-related costs that are not separately reimbursed. In essence, by requiring the inclusion of wholesaler prompt pay discounts in the ASP calculation, CMS has converted physician payments for Part B drugs from the congressionally mandated level of ASP + 6 percent to the lesser amount of ASP + 4 percent.

Based on the statute and congressional language offered at the time of its adoption, what is CMS' interpretation of congressional intent with regard to adequate provider reimbursement for drug reimbursement, and the application of the prompt pay discount to that reimbursement for oncology services?

Answer. The Congress defined the ASP to be an average measure of sale prices across a broad range of classes of trade and, therefore, established that payments to providers represent average drug acquisition costs and not the actual cost experienced by a particular provider or specific class of trade. Further, in establishing that the payment rates are 106 percent of the ASP, Congress established a corridor above the average acquisition cost to address variations in actual costs.

CMS interprets section 1847A(c)(3) to require manufacturers to deduct prompt pay discounts given on sales included in the ASP calculation from the ASP numerator (ASP=sales in dollars/units sold). The language in section 1847A(c)(3) is plain, "In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General that would result in a reduction of the cost to the purchaser."

In the preamble to the CY 2006 Physician Fee Schedule final rule (70 FR 70224), we stated that we lack the statutory authority to permit manufacturers to exclude prompt pay discounts from the calculation of the ASP. We continue to believe the use of "shall" and the limitations on the discretion to include other price concessions in the statutory language do not provide administrative discretion to exclude a statutorily named price concession from the ASP calculation.

CMS—PROMPT PAY DISCOUNT

Question. What evidence is available to CMS that the prompt pay discount is being passed along to the provider of oncology services? If the prompt pay discount is not being passed along to providers, how does CMS achieve the congressional intent to rationalize provider payments with actual costs?

Answer. CMS does not have evidence that prompt pay discounts are or are not being passed along to the providers of oncology services. CMS achieves the congressional intent by implementing the ASP methodology cited in section 1847A(c)(3).

CMS—REGULATORY AUTHORITY FOR REIMBURSEMENT

Question. Congress believes that CMS clearly has the administrative authority to put forward a regulation on provider reimbursement to resolve this issue. Does CMS share this view or is additional legislation necessary?

Answer. CMS does not believe it has the regulatory authority to exclude prompt pay discounts from the ASP calculation. The ASP statutory language is plain and provides limitations on modifying price concessions. We believe the section 1847A(c)(3) authority to adjust the price concessions is limited to those price concessions that would ultimately lower the ASP, whereas removing prompt pay discounts from the ASP calculation would increase Medicare expenditures.

QUESTIONS SUBMITTED BY SENATOR TOM HARKIN

MEDICARE FRAUD

Question. Mr. Secretary, as you know, I have a long record of fighting fraud, waste, and abuse in the Medicare and Medicaid programs. I know that CMS has addressed the issue of fraud in payments to suppliers for power wheelchairs. However, there is still concerns among legitimate suppliers that CMS is not doing enough to root out suppliers that are not legitimate.

I understand that CMS is developing tougher quality and accreditation standards for suppliers. When will these standards be released? And what is CMS doing to make sure that they only issue supplier numbers to legitimate providers? Are CMS's efforts to root out fraud and abuse in this area being hampered by a lack of resources?

Answer. CMS plans on issuing new draft quality standards for suppliers on its website this summer. CMS will then solicit accrediting organizations to review suppliers and assure that they meet the new quality standards. We anticipate that accreditation activities will start before the end of calendar year 2006. Currently, to ensure that only qualified suppliers are issued supplier numbers, we perform site visits prior to enrollment and re-enrollment (which is required every 3 years). We also perform additional reviews of potentially questionable suppliers. These reviews focus on questionable suppliers located in geographic areas where there is a high concentration of fraud and suppliers who have questionable patterns of billing and/or high claims error rates.

CMS—POWER WHEELCHAIRS

Question. On April 6 of this year, CMS published a new final rule that requires that power wheelchairs suppliers review a beneficiary's medical records and determine if a physician's prescription is supported by medical evidence before a power mobility device will be prescribed. What documentation are suppliers required to verify before filling a prescription for a power mobility device? Will CMS issue guidance for suppliers on documentation requirements—including the level of specificity of the documentation—in order to clarify any ambiguities regarding filling a legitimate prescription?

Answer. CMS would like to note that during the comment period of the interim rule, some suppliers noted that they were already experiencing a significant improvement in the timeliness, completeness and substantive content of medical record documentation submitted by physicians since the interim rule became effective. Along with the positive feedback from suppliers, CMS has not received any significant concerns from physician groups or other treating practitioners on this topic. In fact, one professional organization representing over 94,000 physicians and medical students expressed support for the elimination of the certificates of medical necessity (CMNs) for power mobility devices (PMDs).

As you are aware, the CMN for PMDs was eliminated. The CMN was originally designed to improve claims submission by allowing electronic transmission of certain data. Unfortunately, some in the industry saw the CMN as a substitute for evi-

dence of a physician's independent comprehensive examination and analysis of whether a PMD was medically necessary. Despite CMS' and its contractors' statements to the contrary, these suppliers treated the CMN as the ultimate instrument in determining coverage. Some suppliers went so far as to hire physicians to fraudulently complete CMNs. Furthermore, our analysis of claims has found that in approximately 45 percent of cases, statements claimed in the CMNs were not supported by the source information in the patient's medical chart.

Instead of a CMN, the Durable Medical Equipment Regional Carriers (DMERCs) will rely on the patient's medical chart to determine medical necessity. We are concerned that a one-page scripted form would not protect the Medicare program or its beneficiaries in the same way that source information culled directly from a patient's medical record would. The CMN did not help physicians or treating practitioners better document their patients' clinical needs for a PMD, it did not ensure that beneficiaries always received appropriate equipment, and it did not serve as an effective deterrent to fraud and abuse. We believe the beneficiary's physician or treating practitioner is in the best position to evaluate and document the beneficiary's clinical condition and PMD medical needs, and good medical practice requires that this evaluation be adequately documented. Thus, to minimize the documentation requirements for providers while assuring that documentation is adequate, physicians and treating practitioners will now prepare written prescriptions (as required by MMA section 302 and the final rule) and submit copies of relevant existing documentation from the beneficiary's medical record, rather than having to transcribe medical record information onto a separate form such as a CMN.

The rule describes the information that must be included in the written prescription: beneficiary's name, date of the face-to-face examination, diagnoses and condition that the PMD is expected to modify, a description of the item being prescribed, the length of need, the prescribing physician's signature and date of signature. This model provides structure while maintaining appropriate flexibility for the prescribing physician or treating practitioner. Only about 10 percent of physicians and treating practitioners prescribe a PMD for a Medicare beneficiary in any given year, and the majority of those physicians and treating practitioners only prescribe one or two PMDs a year. Given the myriad of forms, brochures, requisitions and similar items in a typical physician's office, a requirement to have a specific prescription form handy in the event that it might be needed would impose an unnecessary burden on the physician and other treating practitioners when that form would only be needed once or twice a year for most prescribers, and never actually needed for the vast majority.

Finally, the physician or treating practitioner must sign the prescription for the PMD and is, therefore, accountable for documentation of the medical need for the device. We believe that this required signature and source documents in the patient's chart effectively document the physician's attestation that the medical need for the device is legitimate.

CMS and the DMERCs have provided extensive educational outreach to both suppliers and the medical community pertaining to the documentation requirements for PMDs. Examples of formal communication include CMS program instructions, Medlearn Matter articles, and DMERC supplier articles explaining the new responsibilities of suppliers. In addition, medical review activities vary depending on the situation under review. CMS cannot develop an all inclusive list of documents or information that Medicare contractors may request during audits. When requesting additional documentation, the DMERCs write to suppliers and ask for the specific documentation or information needed for a review. CMS has defined the circumstances under which contractors request additional information in the Program Integrity Manual. Local Coverage Determinations are issued by our contractors to describe in more detail the conditions under which Medicare payment is made. This additional documentation is only collected during the course of medical review audits and does not need to be collected for all claims.

MEDICAID/SPECIAL EDUCATION BENEFITS

Question. This question concerns Medicaid and special education. I asked Education Secretary Spellings about it at our hearing with her in March, but she said I needed to ask you, so I'd like to do that now.

Under current law, Medicaid pays for the cost of covered services for eligible children with disabilities. School districts can also be reimbursed by Medicaid for the transportation and administrative costs they incur in providing these services. But now the administration wants to prohibit schools from getting reimbursed for those costs. In fiscal year 2007, schools are expected to receive $615 million from Medicaid for transportation and administrative costs. If this change goes through, they'll have

to pay the $615 million themselves, and many will have great difficulty doing so. I'm concerned about this, because if schools can't pay the transportation costs to children with disabilities, the children won't end up getting the services.

Does CMS plan to implement this cut? If so, where do you recommend that schools find the money to make up the difference?"

Answer. Appropriate Medicaid services will continue to be reimbursed as allowed under current law. However, claiming for certain Medicaid services in school settings has proven to be prone to abuse and overpayments. Schools provide a wide range of medical services to students, which mayor may not be reimbursable under the Medicaid program. Problem areas include but are not limited to school bus transportation and administrative claiming, as well as direct medical services. The fiscal year 2007 budget proposes administrative actions to phase out Medicaid reimbursement for some services, including school bus transportation and administrative claiming related to Medicaid services provided in schools.

According to section 1903(a)(7) of the Social Security Act (the Act), for the costs of any activities to be allowable and reimbursable under Medicaid, these activities must be "found necessary by the Secretary for the proper and efficient administration of the plan" (referring to the Medicaid State Plan). Additional authority derives from section 1902(a)(17) of the Act, which requires that States take into consideration available resources. Through the authority of these statutes, the administration proposes to prohibit Federal reimbursement for transportation provided by or through schools to providers.

HHS has had long-standing concerns about improper billing by school districts for administrative costs and transportation services. Both the Department's Inspector General and the General Accountability Office (GAO) have identified these categories of expenses as susceptible to fraud and abuse. GAO found weak and inconsistent controls over the review and approval of claims for school-based administrative activities that create an environment in which inappropriate claims generated excessive Medicaid reimbursements. Audit findings from States where the OIG conducted administrative claiming audits have shown egregious violations. Proper and accurate claiming for administrative services has not been carried out in compliance with applicable Medicaid regulations. Overall, the leading conclusions from these audits are that most States use an improper allocation methodology and insufficient attention is paid to the details of the claiming process.

The fiscal year 2007 President's budget includes a regulatory proposal that would prohibit Federal Medicaid reimbursement for Medicaid administrative activities performed in schools. It additionally proposes that Federal Medicaid funds will no longer be available to pay for the transportation to and from school related to medical services provided through an Individualized Education Program (IEP) or Individualized Family Service Plan (IFSP).

Schools would continue to be reimbursed for direct Medicaid services identified in an IEP or IFSP provided to Medicaid eligible children, such as physical therapy and occupational therapy that are important to meet the needs of Medicaid-eligible students with disabilities, as long as the providers meet Medicaid provider qualifications. CMS estimates that these proposals will save $0.6 billion in fiscal year 2007 and $3.6 over 5 years.

SPECIAL EXPOSURE COHORTS

Question. The Labor HHS Appropriations Act of 2006 (Public Law 109–149) requires NIOSH to prepare a report within 180 days of enactment evaluating whether there are additional radiosensitive cancers not already on the list of 22 cancers eligible for compensation under the Special Exposure Cohort provision of EEOICPA and RECA that should be eligible for compensation. Will NIOSH deliver this report to Congress on schedule?

Will NIOSH solicit comments from experts in radiation epidemiology before submitting this report?

Answer. NIOSH is currently working on finalizing this report and is seeking comments from a set of experts with diverse expertise and perspective, including experts in radiation epidemiology. The report will be peer-reviewed prior to submission. We are working as quickly as possible to obtain comments/edits from the outside reviewers to expedite the process.

Question. The Office of Management and Budget recently issued a "Passback" memo to the Department of Labor, which called for options to "contain the growth in benefits" from new Special Exposure Cohorts under the Energy Employee Compensation law. To accomplish this, the memo outlines options including administration clearance of all Special Exposure Cohorts before a decision is made by you as Secretary of Health and Human Services. Has your Department formulated a legal

and policy response to the OMB memo and if so, could you please share that response with the Committee?

Answer. The National Institute for Occupational Safety and Health (NIOSH) is responsible for receiving and scientifically evaluating petitions from classes of workers seeking inclusion in EEOICP A's Special Exposure Cohort. NIOSH carries out this responsibility under regulations promulgated in May 2004, and amended in December 2005, to make the rule consistent with the amendments to EEOICPA contained in the Ronald W. Reagan National Defense Authorization Act for fiscal year 2005. In fulfilling this duty, NIOSH evaluates the feasibility of scientifically estimating radiation dose for workers in the class that is petitioning for inclusion in the SEC. If a dose estimate is not feasible, NIOSH evaluates whether or not the health of the workers in the proposed SEC class was potentially endangered by their radiation exposure.

NIOSH presents its scientific and technical evaluation findings and recommendations to the Presidentially appointed Advisory Board on Radiation and Worker Health (the Board), a chartered Federal Advisory Committee. The Board considers the NIOSH evaluation and then makes a recommendation to me to either add or not add the class of workers to the SEC. My decision about whether or not to add the class members to the SEC is based on the following: the requirements of the law and the above-mentioned regulations, the NIOSH findings and its recommendation to the Board, and the recommendation of the Board.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

HEALTH CENTERS PROGRAM

Question. I would like to express my sincere appreciation to Dr. Elizabeth Duke for her continued support and interest in the extension of health care service delivery networks to the underserved residents in some of the most geographically isolated communities in Hawaii. In particular, I am pleased with consideration to the future establishment of a health center on Lana'i. Through the establishment of these health centers, significant improvements have been noted in access, quality, and continuity of care. All of which are integral to the early detection, diagnosis and intervention in a myriad of potentially debilitating diseases.

Answer. Thank you for your support of our work in the Health Centers program. This program is integral to our mission to enhance the health and well-being of Americans by providing for effective health and human services

EMERGENCY MEDICAL SERVICES FOR CHILDREN

Question. As expressed last year, I am very concerned that once again the Emergency Medical Services for Children (EMSC) program has not been included in your budget. It can not be stressed often enough that the emergency care and resuscitation of children is uniquely different from adult resuscitation. One size does not fit all in the emergency care of children. There is great disparity in the quality and availability of emergency services for children across this country. While other programs are directed at ensuring the adequacy of adult emergency care services, this is the only program specifically directed at saving the lives of children. How does the Department plan to ensure that America's children receive the emergency care they deserve with no targeted funding?

Answer. States, through the Maternal and Child Health Block Grant program, can continue to fund these specialized services.

BACCALAUREATE TO DOCTORAL PROGRAMS

Question. A long-standing supporter of the National Institute for Nursing Research, I am pleased that the administration has continued funding of this program. However, what impact will the $1 million reduction have on the National Institute of Nursing Research's development of initiative that supports fast-track baccalaureate-to-doctoral programs? These programs were proposed to help increase the number of nursing faculty and in turn decrease the number of qualified nursing school candidates who were turned away in prior years.

Answer. The overall reduction of $792,000 in the fiscal year 2007 budget request of $136.6 million for the National Institute of Nursing Research (NINR) will have no impact on its programs that fast-track baccalaureate-to-doctoral nurses to increase the number of nursing investigators. These programs are supported within the Research Training mechanism in NINR, and the fiscal year 2007 President's budget maintains the current level of support of this activity. NINR remains committed to developing the next generation of nurse scientists. NINR encourages and

supports strategies to change the career trajectory of nurse scientists. The Institute emphasizes early entry into research careers, including fast-track baccalaureate-to-doctoral programs, and supports pre-doctoral and postdoctoral nurses who are the future researchers and nursing faculty.

QUESTIONS SUBMITTED BY SENATOR HERB KOHL

GENERIC DRUGS/FDA

Question. The FDA currently has a backlog of more than 800 generic drug applications—an all-time high—and FDA officials expect a record number of generic applications this year and an even larger backlog. The congressional Budget Office estimates the use of generics provides a savings of $8 to $10 billion to consumers every year, and that doesn't include the billions of dollars of savings to hospitals, Medicaid and Medicare. It is now more important than ever that we speed less expensive generic drugs to market.

Secretary Leavitt, do you support an increase in the FDA budget to help reduce the backlog? How much do you believe the FDA needs to efficiently reduce the backlog and pass along the savings to Americans and the Federal Government?

Answer. First, let me state that I understand that Congress and the public are concerned about the high cost of prescription drug products. I believe that generic drugs play a very important role in granting access to products that will benefit the health of consumers and the government. Prompt approval of generic drug product applications, also known as abbreviated new drug applications, or ANDAs, is imperative to making generic products available to American consumers at the earliest possible date. This has been a high priority for FDA as it has been for me during my time here at HHS. I believe that the process improvements that FDA is currently implementing along with the investments we continue to make in generic drugs offer the best promise for reducing ANDA review time.

FDA has made significant investments to improve the generic drug review process with the funds appropriated by Congress. In fiscal year 2007, FDA plans to spend $64.6 million relating to generic drugs, including $29 million in the Office of Generic Drugs, or OGD. This level represents an increase of more than 66 percent from the comparable fiscal year 2001 amount, which has resulted in a lower median review of 2 months.

FDA has made significant process improvements to increase the efficiency of the ANDA review process. In fiscal year 2005, OGD focused on streamlining efforts and took steps to decrease the likelihood that applications will face multiple review cycles. OGD instituted additional enhancements to the review process such as early review of the drug master file as innovator patent and exclusivity periods come to an end, cluster reviews of multiple applications, and the early review of drug dissolution data.

In fiscal year 2006, FDA is building on these process improvements. FDA began a major initiative to implement Question-based Review for assessment of chemistry, manufacturing, and controls data in ANDAs. This mechanism of assessment is consistent with the International Conference on Harmonization Common Technical Document and will enhance the quality of evaluation, accelerate the approval of generic drug applications, and reduce the need for supplemental applications for manufacturing changes.

FDA's OGD will continue to institute efficiencies in the review process to facilitate the review and approval of ANDAs in fiscal year 2007 and beyond. FDA will also continue to work closely with generic manufacturers and the generic drug trade association to educate the industry on how to submit applications that can be reviewed more efficiently and that take advantage of electronic efficiencies that speed application review. FDA will also work with new foreign firms entering the generic drug industry. It will take time for these new firms to understand the requirements for generic drug product applications. However, in the long-term, these efforts will shorten overall approval time and increase the number of ANDAs approved during the first cycle of review.

With the process improvements stated above and the investments we continue to make in generic drugs, FDA will continue to reduce ANDA review time and deliver safe and effective generic drug products to the American public.

PROGRAMS SERVING OLDER AMERICANS

Question. Some of the most painful cuts in this budget are programs under the administration on Aging, which takes a $28 million hit in programs like Meals on Wheels and Family Caregiver Support Services. That means that while Wisconsin's

senior population continues to grow—from 705,000 senior citizens in 2000 to 730,000 seniors this year and 1.2 million seniors by 2025—this budget does not account for the growth in the need for services.

In addition, this budget proposes to eliminate Alzheimer Demonstration grants. The Wisconsin Alzheimer Association is in its first year of a 3-year grant, where they are working with Jefferson County to open a dementia care clinic at a hospital in Fort Atkinson. It is the first of its kind and the only one in the area. They would lose their funding after this year should this budget prevail.

How do you explain the administration's plan to cut these vital programs when our aging population is growing?

Answer. The fiscal year 2007 President's budget includes the elimination of the Alzheimer's Disease Demonstration Grant to States Program (ADDGS), Preventive Health Services program, and small cuts to other AoA programs including a reduction of $906,000 to Home-Delivered Nutrition Services and $1,980,000 to Family Caregiver Support Services. These reductions reflect an effort to reduce the deficit while focusing on programs that provide needed services most efficiently.

For 14 years under ADDGS, demonstrations in almost every State have highlighted successful, effective approaches for serving people with Alzheimer's. Now, it is time to put these models and the lessons that have been learned to work by moving them into AoA's core services programs—especially the National Family Caregiver Support Program—as a number of States have already done.

Preventive Health Services is a limited, formula-grant funding stream intended to foster the provision of health promotion/disease prevention services in the context of the core community-based long-term care services of the National Aging Services Network. AoA's proposal under the Choices for Independence initiative supports the same type of evidence-based health promotion and disease prevention.

The Home-Delivered Nutrition Services and Caregiver Support Services programs have demonstrated efficiencies in leveraging Federal dollars. In addition, demonstrations such as Choices for Independence are aimed at increasing even further the efficiency of these programs. While reductions in Nutrition and Caregiver services reflect an effort to reduce the deficit, they also reflect an effort to target reductions in programs that have the greatest potential to maintain service delivery with fewer dollars.

RURAL HEALTH

Question. Secretary Leavitt, there are a number of programs within your Department aimed at bolstering rural health. Wisconsin, one of the biggest beneficiaries in the country, received over $600,000 from the Rural Hospital Flexibility Grant program last year. This funding is used at over 60 rural hospitals that serve anywhere from 10,000 to 20,000 patients per year. The President's budget proposes to eliminate the Rural Hospital Flexibility Grant program, the Rural and Community Access to Emergency Devices, and Area Health Education Centers.

How are rural communities expected to meet their unique health care challenges when their resources are being slashed?

Answer. The Medicare Prescription Drug, Improvement and Modernization Act (MMA) will increase Medicare spending in rural America by $25 billion over the 10 years following MMA enactment, substantially increasing funding for hospitals and other rural health providers. This Act serves as a catalyst in rural communities by increasing payments to hospitals, health professionals and other services. In addition, the budget includes an additional $181 million to provide added direct health services to underserved communities through 302 new and expanded health center sites—about half of which are likely to be in rural areas.

MEDICARE DRUG BENEFIT ENROLLMENT DEADLINE

Question. Less than 2 weeks remain for most Medicare beneficiaries to sign up for prescription-drug coverage without penalty. Yet last week a Kaiser Family Foundation poll found that only 55 percent of seniors realize the deadline is May 15, and only 53 percent know enrolling after the deadline will cost 1 percent more per month. Earlier this year, the Senate voted to give you authority to extend the enrollment deadline, but the House has not yet acted. Do you support Congress passing legislation to extend the deadline?

Answer. We are focused on enrolling people now, while the resources are in place to help beneficiaries get the savings and security of prescription drug coverage. According to the Office of the Actuary at CMS, keeping the current May 15th deadline encourages beneficiaries to take action and enroll. The actuaries believe that extending the deadline would likely decrease overall enrollment in 2006 as pressure on beneficiaries to enroll would be diminished. However, in light of the cost effects

on our vulnerable populations, we have recently waived late-enrollment penalties for beneficiaries approved for low-income subsides if they enroll in a drug plan by the end of 2006.

Proposals to extend the enrollment deadline beyond May 15 include no funding for Medicare to maintain the high level of enrollment support that is available right now. Beneficiaries should be encouraged to take advantage of outreach resources like the 1–800 MEDICARE telephone line. There are short waiting times now and individual, one-on-one counseling is available to help people select a coverage plan.

Tens of thousands of beneficiaries are currently enrolling every day, and there is still time to enroll in a plan.

NATIONAL INSTITUTES OF HEALTH FUNDING

Question. The President's American Competitiveness Initiative states that sustained scientific advancement is the key to maintaining our competitive edge—and I agree with that. The President's fiscal year 2007 budget proposal commits $5.9 billion to research and education in basic science, that is the physical sciences—and I agree with that as well. What I don't understand is why the President would, in the same budget proposal, flat fund the National Institutes of Health and its research into health sciences and biotechnology. Other industrialized countries are making investments to make sure they get a piece of the growing biotech and health care sectors of the world economy—why aren't we?

Answer. In fiscal year 2003, President Bush fulfilled his commitment to complete the historic doubling of the NIH budget, which grew from $13.6 billion in fiscal year 1998 to $27.2 billion in fiscal year 2003. During this 5-year period, NIH was able to fund nearly 11,600 more research grants than it did before the doubling began, representing research ideas that are leading to vaccines, cures, treatments, and other fundamental scientific breakthroughs helping to open up even more new opportunities for improving human health.

With the fiscal year 2007 budget request of $28.6 billion, the NIH budget will have grown by +$8.1 billion, or +40 percent, during this administration. While the fiscal year 2007 request for NIH is a straight-line from the fiscal year 2006 level, NIH plans to continue to make strategic investments in trans-NIH initiatives and priorities within its available funds. These include increased support for new investigators, new research project grants, and the NIH Roadmap for Medical Research, a new initiative on Genes, Health and the Environment, and expansion of the Clinical and Translational Science Award program launched in fiscal year 2006. The NIH budget also includes increased investments in national priorities related to developing biodefense countermeasures and pandemic influenza diagnostics, vaccines, and therapeutics. These initiatives will preserve our investment in biomedical research and support medical advancements that will make healthcare more predictive, personalized, and preemptive and thus, improve the length and quality of human life.

NIH welcomes the proposed increase in funding for the physical sciences. Biomedical research is becoming increasingly multi-disciplinary, requiring both science and mathematics to conduct projects in emerging areas of great scientific promise, such as bioinformatics, computational biology, nanotechnology, tissue engineering, and biomedical diagnostic imaging, to name just a few.

SUBCOMMITTEE RECESS

Senator SPECTER. Thank you all very much. The subcommittee will stand in recess to reconvene at 8:30 a.m., Friday, May 19, in room SD–192. At that time we will hear testimony from the Hon. Elias A. Zerhouni, M.D., Director, Department of Health and Human Services.

[Whereupon, at 11:30 a.m., Wednesday, May 3, the subcommittee was recessed, to reconvene at 8:30 a.m., Friday, May 19.]